HOW THE FEDERAL GOVERNMENT CAN BE A BETTER PARTNER TO OREGON'S BIO-TECHNOLOGY INDUSTRY

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY

OF THE

COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

PORTLAND, OR, OCTOBER 17, 1994

Printed for the use of the Committee on Small Business

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HOW THE FEDERAL GOVERNMENT CAN BE A BETTER PARTNER TO OREGON'S BIOTECHNOLOGY INDUSTRY

MONDAY, OCTOBER 17, 1994

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:41 a.m., at Portland City Hall, Council Chambers, 1220 S.W. 5th Street, Portland, Oregon, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman WYDEN. The subcommittee will come to order.

We appreciate all our guests and would like, in the interests of time, if they could to be seated and we'll go forward.

Today the Subcommittee on Regulation, Business Opportunities, and Technology will examine how the Federal Government can be a better partner to Oregon's promising biotechnology industry. I'm especially pleased that we're having this hearing.

It is essentially a hearing at the request of Congresswoman Furse, who has had a special interest in biotechnology in her time in the Congress. Suffice it to say, her district probably has most of the biotechnology companies in the State. She has been an active participant in the debate about biotechnology with her work is environmental biotechnology issues, and also she has been a champion of protecting the right of small biotech companies to have a stock option as they wait to come up with capital in tough financial markets. So I am very pleased to be able to team up with my friend and colleague, Congresswoman Furse.

Let me just make a very brief opening statement, so that the record is clear. The Oregon Biotechnology Association defines biotech as the industrial use of living organisms to enhance life. We feel that this area is a potential Oregon economic bonanza, with an opportunity to create family wage jobs through the development of products that can heal disease, feed the hungry, and clean up the environment.

Our State officials, our State economic development officials, recently named biotech 1 of the 13 key industries in the long-range plan for the State's economic development. But I think Congresswoman Furse and I feel that even though the Oregon biotechnology industry is off to a very promising start, it's still in the cradle and the Federal Government needs to take steps to foster its growth.

One of the special areas that we are concerned with is ensuring access to capital. According to the Ernst and Young ninth annual report on the biotech industry, financing is now the most critical challenge for biotechnology. The industry is getting better at raising money, but research and development requirements continue to rise. What is especially relevant is median survival index, which measures a firm's cash on hand divided by the rate at which it spends, is just 25 months, which means it is down from 34 months a year ago. Only a little over 20 percent of the firms have enough cash to last 5 years.

We understand the urgency behind the call for expanding access to capital. We're going to be exploring this with our witnesses today.

Recently I introduced the Entrepreneurship Promotion Act, which is a special legislative initiative which would increase access to capital for our small companies by allowing the owner of a small firm, when they sell their firm, to reinvest the proceeds in another small firm without any significant tax bite. It would allow us to do for our country's small business sector what we've done for home ownership. I'm very hopeful that we'll be able to get that issue enacted early in this Congress.

The other area that we have been asked to look at by the industry are issues relating to federally funded research. For example, the Federal Government has agreed to spend $3 billion over 15 years on a massive effort to map gene sequences in human DNA. This project is known as the Human Genome Project.

We're very hopeful and are interested in having more of those research dollars allocated to Oregon research facilities, and we're going to be exploring that issue today.

There will be other questions I know that will come up. We're also interested in the matter of patents. This subcommittee has done considerable work in this area and been able to get some additional patent examiners devoted to biotech in the Patent Office, but as our witnesses and Oregon businesses know, there are also problems relating to the standards that are being used by the Patent Office in reviewing biotech products. We're anxious to review those as well.

So with that, let me turn to my friend and colleague who, as I say, has really been the champion both for her district and stock options, envirotech issues, the leader in this area, and I look forward to the chance to work with her.

[Chairman Wyden's statement may be found in the appendix.]

Ms. FURSE. Well, I want to thank you very much for giving me this opportunity. It's a pleasure to be here. I think we, all of us, take our local treasures very lightly. We are very fortunate because Congressman Wyden is not only a leader in Oregon on this issue but known nationally for being the support of small businesses and particularly start-up businesses.

I think that we are very fortunate to have this hearing. I'm very fortunate to work with him. He has helped me so much as a new Member with this particular interest that I have in environmental technology. As you know, the idea of new businesses is nothing new to Oregonians. We are an entrepreneurial State, and there are so many promising new businesses here that it really is no wonder

that we have this well-deserved national reputation for being on the cutting edge.

I think it is also no surprise that Mr. Wyden's chairmanship of this committee makes the difference on the national scene. We are fortunate because our local issues are taken to a national scene.

Now, we all know that biotechnology is on the cutting edge, but it also is on the cutting edge, particularly for the Northwest. It holds great promise for us. However, I think for too long Government and industry have in some ways been working against each other.

Fledgling industries are built on the brains and brawn of small entrepreneurs, and very often they have had to do that without—not only with no assistance from the Government, but in fact in some ways with some problems, some blocks from the Government. So as we move more and more towards a global economy, we know that we need to be more involved, all of us, the Government and the businesses, working together.

This hearing is about that. It is about: How can Government help biotechnology, but also how can it get out of biotechnology's way if that is what is needed.

The three panels, as Congressman Wyden mentioned, will be on the access to Capital, one on Environmental Biotechnology, and one on the Human Genome Project. These are excellent opportunities for us to overview the relationship between industry, science, academia and the Government in biotechnology as an industry in the United States. This is heightened by the importance in Oregon because it has been targeted in Oregon as one of the key industries for this region's economy. We know that this is an important project, important industry.

I am very pleased that we have a panel today on environmental biotechnology. As you know, I was fortunate to be the coauthor and worked to pass the Environmental Export Promotion Act that was signed by the President this week. This act will help all Oregon businesses and other national businesses who work this environmental technology, goods and services, help them find customers around the world.

We know this is a booming global economy item. We think that it will go to $600 billion globally by the year 2000. We need to be part of it. The other great thing about environmental technology is not only is it a new business, one that we need to export around the world, it is a high wage business. It is something where people will get the family wage jobs. It is a fabulous business because it cleans up on high wages but it also cleans up the globe.

It is a great honor for me to be here today, and I want to thank Congressman Wyden for holding this hearing here in Portland.

Thank you.

[Ms. Furse's statement may be found in the appendix.]

Chairman WYDEN. Well, I want to thank my colleague, and I did note that your bill was signed this week. That's a real shot in the arm for Oregon. I commend you for that.

Let's call our first panel then, a particularly important panel, dealing with the access to capital issue: Mr. Alan Timmins, chief financial officer of AntiVirals; Mr. Gerry Langeler, Olympic Ven-

ture Partners; and Mr. Art Hiemstra, regional vice president, Silicon Valley Bank.

If you three will come forward. Gentlemen, it is the practice of this subcommittee to swear all the witnesses who come before us. Do any of you have any objection to being sworn as a witness today?

Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. We're going to make your prepared statements a part of the hearing record in their entirety, and we appreciate the leadership all of you have shown.

Why don't we just begin with you, Mr. Timmins. Welcome.

TESTIMONY OF ALAN TIMMINS, CHIEF FINANCIAL OFFICER, ANTIVIRALS, INC.

Mr. TIMMINS. Thank you, Congressman. My name, as you said, is Alan Timmins. I'm the executive vice president and chief financial officer of a company called AntiVirals, which is a——

Chairman WYDEN. I think you have—I can already see people straining to hear a little bit. If we can get you to put that right in front of you. Perfect.

Mr. TIMMINS. [continuing.] which is an Oregon biotechnology company founded in 1980. I've been asked to testify this morning on the state of capital access for the biotechnology industry, as well as for your proposed bill, H.R. 5201, which would amend the Internal Revenue Code.

First off, I'd like to say that as you outlined in discussion or description of the panels coming up, biotechnology used to be a very narrowly defined industry, but now it's expanded to include not only drug development companies like my own, but also diagnostic companies and companies that develop certain agricultural products. The means needs of those companies are similar, but they vary based upon the size of markets that each of those companies tries to attack.

The first question, of course, and the most important question is: What really are the capital needs of a biotechnology company? Well, in the drug development industry, which my company participates, the needs are truly staggering. The cost of bringing a drug from the development process all the way to the market has been estimated to fall within a range of $100 to $500 million. The average is thought to be somewhere between $150 and $200 million.

Those numbers are indeed significant, because if you think about an average small company like my own, that's many times the funding that we've been able to raise over our 14-year history. Diagnostic companies and agricultural companies have somewhat smaller needs, but each of those companies' needs are based upon three things, one being the complexity of the technology involved, are they working on the leading edge where no scientist has ventured before, or are they making manipulation of some currently existing technology; second, the degree of capital intensiveness in the development cycle; and third, the level of FDA approvals required.

What's all this capital used for that I have discussed? Well, there's really four purposes for capital. First off and most impor-

tant, particularly for development company, is a highly trained and highly educated work force. For a company like my own, we're talking about mainly Ph.D. chemists and molecular biologists. They have to occupy the key research posts. Later on in the development cycle, companies will need process engineers to help them bring their scientific theories into a market manufacturable product.

The second use for capital is for expensive instrumentation. Unfortunately, a company like my own can't walk into a J.K. Gills, for example, and buy the instrumentation that we need to perform our experiments. In fact, the highly sophisticated instruments that we do buy often need to be modified or customized for our particular portion of the science.

Third, companies need capital for facilities that are designed and maintained in accordance with both the FDA's GMP or good manufacturing practices standards, and for GLP, good laboratory practices. To give you a concrete example there, as our company nears FDA clinical trials, we'll need to build a pilot plant. The purpose of that pilot plant is solely to provide compounds for FDA trials. The cost of that plant has been estimated at somewhere between $4 and $5.5 million. That's just to get into the FDA clinical trials ball game, $4 to $5.5 million.

The fourth use of capital is the extensive, expensive and exhausting testing that each product needs to go through in order to pass FDA trials, and we'll talk about that a little bit more in a moment.

The sources of capital for the biotech industry have remained relatively static in the 12-year history of the industry. But they have changed kind of their order in terms of preference and in terms of their accessibility. Initially, when the industry was young, Government grants were kind of the preferred way for academicians and researchers to fund their projects. Those grants were designed to stimulate innovation, give the scientist some seed money to work and develop his ideas.

Second, the scientist would go to venture capitalists like Mr. Langeler and later to an IPO market, initial public offering, sale of their stock to the public. Smaller in terms of their desirability and in terms of their frequency of being tapped were corporate partnerships and/or private placements of stock to wealthy individuals or foundations.

Now, however, there has been a reshuffling in the importance of those capital sources and in how the frequency in which they're accessed. First and foremost, biotechnology's seed corporate partnerships. What that does is it gives them a ready source of often large amounts of capital, with major pharmaceutical partners. It also seems to give them and the marketplace a stamp of approval or credibility for their technology because what we're talking about here isn't something like making a garden tool. It's something that's very hard to understand, even for the most sophisticated of scientists. If it wouldn't, it would have been done before. So those corporate partnerships are now the most sought after source of found funding.

Second and also very important again are the venture capitalists and the initial public offering markets. Those are critical but biotechnology companies over time, and the market itself, have learned an important lesson. That is that those biotechnology com-

panies must achieve or appear to achieve significant scientific benchmarks before venture capitalists are attracted to the company and before the public market is attracted to the company at a valuation that in essence isn't giving away the store in order to fund future development.

The original highly sought after Government grants now is really a minor portion of capital accessing for the biotechnology companies such as mine. The reason for that is that, A, it's not really available, and B, scientists look at the cost and benefit of going through the application process and find that it really isn't worth it. It takes almost as much or more effort to apply for a grant as it does to sell your stock to the public. So that has really curbed the use of Government grants today in the biotech industry.

What are the barriers to funding for a biotechnology company? I see two things as the major barrier. Obviously, cost is number one. Those figures that I gave you before, $150 to $200 million, is an average cost to bring a drug to market. Huge barrier. Second big barrier is the time to market. When we're talking about a company such as my own which has been in business for 14 years, we still don't have a product on the market.

Now, you can attribute that to a number of things, but I'll tell you the average time to market for a company in drug development is 10 to 12 years. That's from the start of the idea through FDA approvals and all the way to having a salable product. That's a long time. That's a very long time.

Mr. Langeler can address this better than I can, but I can tell you that investors don't want to see their money tied up in ultra high risk things for ultra long periods of time. They want to put their money in and in a reasonable time get their money back out with a reasonable return. Biotechnology, because it's high risk and it has that additional time element that's longer than any other industry that I'm aware of, requires investors to look at an almost super what they call hurdle rate, which is the rate at which they feel their money must bring in return. That's not, in the 5 or 6 percent bracket. That's 40, 50, or 100 times, 2 to 3 times what they invest in the number of years that it takes in order to bring a product to market. That is indeed very significant.

When you think about the biotechnology industry trying to raise capital, we're not just one industry and the only industry or only group of companies that are looking to get capital. We're competing with Governments that make farm implements, companies that invest mutual funds, companies in every other industry. So in a competitive environment, we have a higher degree of risk because we're in effect where no scientist has ventured before, and second, we take a longer time to either prove out or disprove what our theories are.

Those are incredibly significant and slowing impacts on the amount of capital and the ease with which capital is accessed for companies likes ours. There have been—part of the timing issue, though, and part of the importance I think of this meeting, is hopefully I can emphasize to you that a major portion of that time is, and cost, is due to the FDA approvals process.

In the United States, it's longer, it's costlier, than it is in certain European countries. I find it shocking to visit other companies,

major pharmaceutical companies, talk about product introduction, and their response is, well, here are the European countries where we'll introduce that product first, because if we introduce a product in the United States, it will be years before it reaches the market. So there can be a return of capital, but it's overseas, based upon U.S. technology. I find that shocking.

I think the critical element then that I am trying to emphasize here is that the time and the costs of the FDA approval cycle must be reduced.

Let's talk a little bit about the proposed legislation, H.R. 5201. I think that that is definitely a step in the right direction and it will help biotech companies in raising capital. Any investor looks at two things when they're thinking about raising capital. That is the risk associated with their investment, and the return that they expect to get from that investment.

I think that H.R. 5201 does a very good job of addressing the return side of the equation. That is, if I invest, I will be able to get more significant returns because I'm not saddled with taxation at the time that I divest my investment if I in turn go ahead and invest again.

A suggestion that I would make would be to address the other side of the question, which is the risk side of the question. The way I would do that would be through a program of either tax credits, which is fairly common in certain industries or certain cases, or what I call hyper-deductions. That would be a deduction in excess for a loss—a deduction in excess of my investment for a loss that I incur, for example, 110 to 120 percent in deduction for a dollar that I have lost on a small business investment.

A couple of other modifications that I would suggest in H.R. 5201 would be to consistently define what a small business is. Currently there's legislation, the Internal Revenue Code has been modified in the last year, and Section 1202(c) allows for a reduction in the capital gains tax for investments in qualified small businesses.

The definition of a qualified small business there, though, is a company roughly with assets greater than $50 million. Proposed legislation talks more in terms of a small business being a company with $20 million in assets, roughly.

As we've gone through this discussion of biotech companies, I hope you can see that what I'm advocating is to make those two figures consistent, and hopefully at the higher amount, because a company like my own could certainly go through $20 million in cash in a relatively short period of time.

The second thing that I would advise on the proposed legislation, H.R. 5201, would be to clarify the interaction between that existing Internal Revenue Code section and the proposed legislation. It's not clear to me when I read the proposed legislation whether if I make a long-term investment in a small business, over 5 years, and then qualify for the lessened capital gains tax, if I roll that into another small business for a less than 5-year period, am I taxed on the gain at the 28 percent or full capital gains rate, or back at the preferred rate for having—for holding the original investment for 5 years? I think that that is an item that within the bill needs to be clarified.

In summary, I think that the legislation that you have proposed, Congressman Wyden, is very valuable and I think that it will serve

as a very good stimulus to investors to look at small business and to look at biotech companies. To have them look, though, more seriously at biotech companies, I would also advocate the changes that I have discussed. My only other point of emphasis would be to—that something needs to be done to streamline the FDA approval process so that cost and time to market for biotechnology companies is reduced.

Thank you.

[Mr. Timmins' statement may be found in the appendix.]

Chairman WYDEN. Mr. Timmins, thank you. Thank you very much for your testimony. Excellent testimony, and we're going to follow up with you on your suggestions in respect to the legislation. You've got some good ideas there. I want to work closely with you and your association.

Mr. TIMMINS. Good. Thank you.

Chairman WYDEN. Mr. Langeler, welcome.

TESTIMONY OF GERRY LANGELER, GENERAL PARTNER, OLYMPIC VENTURE PARTNERS

Mr. LANGELER. Thank you. Al Timmins has done a marvelous job of summarizing the issues here, so what I will try to do is not tread over the same turf any more than I have to. However, a couple things I might want to reiterate and perhaps one or two where I have a slightly different slant.

I also agree that the fundamental barrier to capital infusion into the biotech industry in Oregon or anywhere else is regulatory. As investors, we look at one thing, which is return prorated over time. That's how we are measured by the people who invest money in us, is return on their investment, which is a time-related phenomenon. So as we look at any biotech investment, we are painfully sensitive to the issue of regulatory timing.

We do not believe that going forward with the public markets will necessarily continue to support public offerings of companies with no sales. The biotech industry is perhaps the lone industry in the history of U.S. finance that has managed to create very large market companies with no sales. That may continue, but we're not going to bet on it.

So when we look to put money into new biotech organizations, we are counting time just as much as we are potential return in our equation, and see the risk rising that venture capital investments in biotech may not be wise, because there may be no liquidity path out the other end, other than acquisition by large pharmaceutical companies.

I would take issue now on a couple things. At the stage Alan's company is in, Government grants can become less important, I would agree. I think in general however Government grant money continues to be very important in helping scientists move from the pure research stage into something that starts to approach development.

Venture capitalists will usually not invest, knowingly, in a pure research stage. We sometimes invest in what we think is a development stage and find out it's the research stage but it wasn't by design. So to the extent that you can influence Government funding of primary research to get those scientists past that initial point to

the point that the science is in fact understood and proven and development on real product that could have commercial value can begin, that would help the venture capital community open its purse and invest.

There is a new class of investors in this field which I would call the huge angels. Angels being private investors, they're now Huge Angels in this geography, most notably Bill Gates and Paul Allen, who will occasionally team up with a variety of commercial bankers, go into large sums of money and venture back to the biotech world. That's great. I think it's very—they may foul up the valuations for those of us trying to make money in the business, but they are providing capital.

I think perhaps an unintended consequence of H.R. 5201 is it may ultimately make Bill Gates and Paul Allen richer. I will tell you that 5201, I think, is an excellent bill in a number of ways. I'm not convinced it will help the biotech industry all that much, because of the very large capital requirements in the biotech industry. It will not be such that private individuals can be the primary funding source. But I think it will spur business start-ups in general tremendously. Therefore, I think it's a good legislation.

I think Alan had some excellent suggestions on improving it, but I think in basis, it's the right direction.

Let me come back to the FDA and the EPA for a moment and just give you two examples perhaps to take away and think about and use when appropriate. One is an Oregon example, one is a State of Washington example. In Oregon, we have what we call Concept Over Bend, environmentally sensitive pest control, bioremediation pest controlling, using membrane technology to deliver naturally occurring pheromones, what the insects use to attract each other, into the environment to confuse the insects so they don't mate so they don't hurt the crops. This is, again, naturally occurring substances emitted into the air.

The regulatory cycle to get that through is measured in multiple years. If you happen to have what is the EPA equivalent of clinical trial, in this case a field trial, and you have bad weather, you can lose a whole season or a whole year for a couple weeks of rain or cold or something else. This is again not genetically engineered substances that we don't understand. It is not toxic chemicals being put in different concentrations and we're trying to understand their effect. This is naturally occurring substances the insects produce today. If concept has to suffer that from EPA, imagine what happens for new chemicals that in fact might be under a little more scrutiny.

Up in Seattle, there is a biotech company, very successful one, called Cell Pro, that takes a technology to isolate individual cells or types of cells in the body. It's first indication through the FDA at this point, going through the FDA, is for breast cancer treatment of chemotherapy patients, where they are actually take your bone marrow and extract out of it just the vital cells that you need to rebuild your immune system after chemotherapy. Again, they're reinjecting only your cells into you.

This company finished its Phase III trials and submitted its report to the FDA last year and may see approval from the FDA in 18 months after doing so. The product is being sold in Europe and

there in fact are people who are living today because of that product in Europe that are not living in the United States perhaps.

Again, this is not to say that the FDA should not do their job, nor the EPA. But I believe that the FDA's mind-set, which is to prevent the next thalidomide, has been taken too broadly across all projects. There needs to be some way to differentiate between a newly developed chemical substance that you don't understand that needs tremendous scrutiny to make sure it isn't the next thalidomide, to different classes of products or devices or substances that can get through much quicker and have some kind of fast track process.

So I would encourage you, when you go back to the next Congress, to work that issue harder because that's the one I think that if we as investors can see a faster path to liquidity so that if in fact the scientists are right and their products work as expected, we can get the returns we're looking for and we will open up our pocketbooks.

In the absence of that, as Alan correctly says, we are not a biotech only investment fund. We invest in software companies. So if we have to make an investment in a software company versus investment in biotech company that have equal opportunity for return but one has a risk of delay on that return that's significant and sort of uncontrollable, we will tend to opt toward the safer path.

Thank you.

[Mr. Langeler's statement may be found in the appendix.]

Chairman WYDEN. Mr. Langeler, thank you. Excellent testimony. We're going to ask you some questions about the approval process as well as follow up on capital access issues here in an moment.

Mr. Hiemstra, welcome.

TESTIMONY OF ART HIEMSTRA, REGIONAL VICE PRESIDENT, SILICON VALLEY BANK

Mr. HIEMSTRA. Thank you. I'm Art Hiemstra, I work for a bank known as Silicon Valley Bank. I am the Northwest regional vice president. We have an office in Beaverton. Our bank works with technology companies, which encompasses biotechnology.

I'd like to again not cover the same ground, but I would like to give you a little bit of perspective on——

Chairman WYDEN. Let me see if I can talk you into moving that mike a little closer. All those soft voices.

Mr. HIEMSTRA. On how a commercial bank can be involved in the process of financing biotechnology companies. From our perspective, the creation of a new company, a new biotechnology company, really takes place when there's a confluence of management talent, scientific discovery, market opportunity and capital. A company missing any of those ingredients will probably ultimately fail. But the one I would like to address is capital.

We've heard that from a time a biotech company is formed until it reaches commercial viability is many, many years, let's say 10 years. During this time frame, a large amount of cash is consumed for salaries, for research and development, for the many things that are needed to take a company from concept to product. I have in my notes that tens of millions of dollars are consumed from an

expert on the panel, it's often hundreds of millions of dollars. At any rate, it's a lot of money. Public and private investors have provided the bulk of this capital.

Our bank has looked at this situation and tried to find ways that we can provide a layer of debt capital to these companies to help finance certain parts of the process and work in partnership with equity investors. That partnership is what's really crucial for us because, as a lender, we need to be repaid and we need to know that the investors are involved for the long haul.

So the involvement of our money follows equity investors and allows a company to use the more expensive equity money on research and development, the basic activity that funds the value in the company, while financing depreciable assets with lower cost debt capital.

As a lender, we take great comfort in a biotechnology or other high technology company that attracts corporate or professional investors, because we know that they are looking at management, at the science, at the market opportunity, and when they conclude, that it's a situation that they should get involved with, there's an implicit and underlying assumption on their parts and on our part that they have thought about the time factor and that they will need to be involved or help to arrange for other financing in subsequent years.

When those conditions exist, we can help to fund the assets and do make available a layer of debt capital on top of the average investment. It is obvious, our activity then is predicated on the continued support of equity investors. As a result, we're concerned with the flow of capital, the flow of capital to investors, from investors to company, and in that whole cycle, so we monitor very closely which parts and which kinds of investors are able to raise capital to invest and take into consideration and are pleased with activities like H.R. 5201 that may encourage the flow of capital from private sources to investors, ultimately to companies.

We think that perhaps tax deferrals like this one make it easier for professional investors to attract capital, but probably more important and maybe more to the point for Oregon, is that it will help smaller, more private investors being encouraged to invest.

Chairman WYDEN. I call them little angels. Mr. Langeler was very interesting, talking more about huge angels. I've been saying if we could just get some more baby angels who would be willing to recycle their earnings and keep capital out there. Excuse me for interrupting.

Mr. HIEMSTRA. We often in Oregon see companies that are unable to attract money from professional investors. It's often not so much that it's a company that's without merit, but it's maybe one that the technology is just too speculative or the market opportunity is too hard to quantify. In other words, it's probably too early in the cycle. These companies often only need a few hundred thousand dollars to make some progress.

Government grants are one source, but the little angels are a source that is really critical in Oregon. It's a source of capital that is very scarce from our point of view. We have seen in other parts of the country that kind of capital flow more readily. It's somewhat of a function of population. It's a function of overall wealth in a

community. But it's a function also of things like taxes. That is a leveling factor that can perhaps encourage private capital to flow into smaller companies.

So we encourage your attention on this kind of bill and particularly in a State like Oregon that does have a private wealth and through education and through hard legislative action like this perhaps flow more readily to the smaller companies who then can eliminate some of the obstacles and later attract larger amounts of capital.

[Mr. Hiemstra's statement may be found in the appendix.]

Chairman WYDEN. Well, thank you. Excellent statement.

Let me recognize my colleague for any questions.

Ms. FURSE. Well, I'd just like to ask, there are two committees I serve on, so I would like to ask from that point of view. One, are there any banking regulation—I ask you first, Mr. Hiemstra, maybe the others, are there any banking regulations that you think particularly make it difficult and cumbersome for biotechnology companies, credit application?

Mr. HIEMSTRA. No. I don't think banking regulations—in fact, I'm not aware of any that are pointed at that industry. As a regulated industry ourself, we need to periodically explain the loans that we make to a Federal regulator representing the FDIC or other body. There is a tendency to look at loans made to companies that have no revenue.

How will you be paid back is the obvious question. We developed a technique, a track record, that has enabled us to work with the regulatory bodies that work with our bank so they're comfortable with our kind of lending. I think it takes time and really takes a close working relationship with the regulator to make that work.

Ms. FURSE. What about you, Mr. Timmins?

Mr. TIMMINS. I should first say that Mr. Hiemstra's bank is probably the most forward looking and progressive of any bank that serves the technology industry. But I think the basic point that he's making, Congresswoman Furse, is that ideas in and of themselves make lousy collateral. Knowing the banking industry, they're not going to loan money based upon no collateral. So that's a critical element.

A company like mine, I'd speak with Mr. Hiemstra about small operating lines of credit, but as a major source of capitalization, we would not look to him.

Chairman WYDEN. Mr. Langeler?

Mr. LANGELER. No comment, thank you.

Ms. FURSE. If I may, one other question, again coming from my committee where I serve on the House Armed Services. Do you look to ARPA as a place where you might get this original research? Now we're going from DARPA to ARPA. Do you see that as a place where we might be looking for more research dollars in the early stock?

Mr. TIMMINS. That is difficult to say. I'm unfamiliar with what application process one would go through. So it would be difficult to say.

Ms. FURSE. Gerry?

Mr. LANGELER. Well, again, I don't know how much has changed since DARPA became ARPA, but looking back in time, DARPA was

historically an excellent source of major research capital, particularly collaborative research capital, where the DARPA agency would encourage various commercial scientific organizations to collaborate their resources and brain power on some larger task, any one of them than any one of them could have undertaken on their own.

If it continues to do that, that's a very healthy process. Because there is no lock on brain power from institution to institution, and to the extent that they can be encouraged financially to collaborate and take on large challenges, that can push the science along more rapidly than otherwise. So I think ARPA funding ought to be a good research funding source.

Ms. FURSE. Thank you. Thank you, Mr. Chairman.

Chairman WYDEN. You all have done a great job, and based on everything I've heard, this matter of access to capital is really the ball game, that if you don't have access to capital, almost everything else is sort of uphill.

I'm curious, how much of the access to capital problem is biotech specific in our country and how much is just representative of the problems small businesses have generally getting access to capital?

Mr. Timmins?

Mr. TIMMINS. Well, I think that the problems that the biotech industry have are perhaps magnified by some of the issues that we've spoken of today, time to market, the absolute cost of getting a product to market. I think that that makes it more difficult than the average industry.

The feature that biotech has also that makes it more difficult to get capital is that it's not readily understandable. It's a sexy idea, but the application on a company-by-company basis is not something that everyone can pick up. In fact, technology for companies such as ours can be explained to various chemists, molecular biologists, and they'll disagree with its merits. So that I think makes it difficult to then turn around to an investor who, while they may be a sophisticated businessperson or a sophisticated investor, they are most unlikely to be a sophisticated scientist where they could really critically evaluate the pluses and minuses of the investment in biotech.

Chairman WYDEN. Let me also, since you've got the microphone, say that I'm going to be glad to follow up with you on your suggestions. I think you know how tough this capital gains fight is. Back before I had my friend in Congress, I was 1 of 70 Democrats who voted with George Bush for his capital gains tax cut.

We weren't able to get it, and one of the reasons the amount is set where it is, is because there is such a struggle to try to get these initiatives even up in front of the Congress because there is substantial opposition. So your ideas are very good and we are going to follow up with you.

Mr. TIMMINS. Great.

Chairman WYDEN. Let me turn now to the FDA approval process and I've had a long interest in this. I know my colleague has as well.

Mr. Langeler, I think you know that part of the problem behind the approval delays is that we are essentially in our country of many minds, not just on biotech issues but on lots of things. What

we want is we want to make sure that there are no thalidomides. At the same time, we want to have approvals for terrific products go through like, grease through a goose. So we want to have both of those things in an ideal world.

I have been working and particularly pursuing legislation to try to fast track the approval process for companies that would be willing early on in a product's life cycle to bring clinical data to the Government and in effect say as a result of our spending our money, our hard earned nickel, to produce this clinical data that you can review independently, we believe we have earned the right to go to the head of the regulatory queue.

Is that something that might help us bridge the gap between these two camps, the one that, has insisted on the longest approval process that makes sure that there's never any risk and those that in effect want it to move through overnight?

Mr. LANGELER. It might be, although to some degree some of that's going on now, so I am not exactly sure——

Chairman WYDEN. Well, it's going on with HIV products, because to their credit, AIDS activists have made that fight. But it isn't going on in a lot of other areas. I think you all know better than I in the device area, we have this ridiculous kind of situation where if you're not being bold and innovative as you three, sometimes you then get to go to the head of the approval process.

Mr. LANGELER. The whole phenomenon around 510(k) which says the substantial equivalent to something on the market today isn't that exciting, is kind of odd in that regard. I believe that there should be—continue to be, clear human clinical trial evidence before products that can affect humans are into the market. I won't argue that at all.

My argument is actually much more from the time clinical trials are done until the time that review process is finished is the lag that I object to. I mean, the example I was using, here is a product that just reinjects your own cells into you, except it's taking bad stuff out, put the good stuff back in. If that takes a couple of years, imagine what it takes—this is after Phase III clinical trials, many, many patients, all the data in, the data has been accepted by the FDA.

Chairman WYDEN. So what would you advocate that the Government require in an instance like that where the data is in? What should the Government do? Should we set a time period?

Mr. LANGELER. I think there is a case to be made that says sort of the equivalent of the sunset law, in reverse perhaps, saying if the Government doesn't stop you, you can sell it within a year. But maybe you have a couple classes of products. This is one where the risk is obviously substantially lower.

If it is a new substance going into humans for the first time, maybe there ought to be a long cycle. But something that says after you finish Phase III clinical trials and the Government has accepted the data which says it thinks the data is clean, regardless of its output or means, then the clock ought to be ticking on the FDA, not on the company.

Chairman WYDEN. I'm sympathetic to that position. In another part of my life, we all serve on a bunch of committees. On the Health Committee that I serve on we have begun to explore this

issue of setting some deadlines. I think it's something that the Congress has got to get to. There's got to be a way for saying that this kind of stuff isn't going to be longer than the Trojan War and this is going to go on and on and on.

Mr. LANGELER. The only thing that scares me about that, the fear of regulatory agencies, is there can be a backlash, an unintended consequence, which is the Agency can say, well, in that case if I come down to the line, I haven't gotten this at the top of my pile of things to work on, I'll just reject it. Put it at the bottom of the stack and start the cycle again.

So there has to be some kind of safeguard to keep overworked regulators, and many of them are overworked, they've got this incredible flood of new technology and products coming out that they're trying to understand, from kind of throwing up their hands.

Chairman WYDEN. Let me just ask one other one. Maybe this one is for you, Mr. Hiemstra. In terms of the Patent Office situation, I know there are hearings that are going on. We seem to have made some headway in terms of getting more people, we seem to have made some headway in terms of some of the old backlog. But now I understand that there are also some problems with respect to the standard setting kind of process for biotech companies, because they in effect, instead of trying to get a patent on an idea, the biotech companies, as far as I can tell, are sort of asked to go through the FDA approval process, when in fact they're just showing up at the U.S. Patent Office to try to get a patent on an idea.

Maybe you could tell us more of what the biotech industry wants and any suggestions you have because we've been at the Patent Office and this subcommittee for a long time and I am very interested in following up with standard setting matter, too.

Mr. HIEMSTRA. I really can't address that in the sense that we don't work with the Patent Office as a bank and it's not an issue that's regularly monitored. But as you described the situation, it seems obvious to me that somebody in the company part A needs it talk to part B. If the FDA is going through this process of approval and it becomes apparent that there's a patentable idea, and often that's known far before the FDA gets involved, those two agencies ought to be talking to each other. We need to shorten that process.

Chairman WYDEN. Are you finding that this is a serious problem as I am hearing reported?

Mr. HIEMSTRA. As a lender, it's not a problem to us and to our industry. I think Mr. Timmins perhaps could address that.

Chairman WYDEN. Maybe I just asked the wrong fellow. Mr. Hiemstra is being polite and telling me diplomatically I should have asked you, Mr. Timmins.

Mr. TIMMINS. In the banking business, I think that's passing the buck is the term. Actually, the patent—our company has been fortunate in that, in obtaining patents for our critical technology, we have found that we generally are working in an area that has not attracted a great deal of interest on the patent side from other companies at this point in time.

What becomes a problem, however, is when companies try to patent, in effect they make a reservation for technology that they might have or something that they would like to do and obtain a

patent over, say, a certain area of the genome, which is where they could make or develop a drug for a certain area of the genome, and if someone else developed a different drug or different way to attack that area of the genome, they would be precluded through the Patent Office.

I think what you will see over time is that it will just become basically a logjam in the legal system, because companies will proceed and go about their business with the thought that, well, if I beat them to this target, then I'll make them sue it out of me, I'm make them sue me to exercise their patent. So I think there is a potential for a huge logjam in the patent process.

Chairman WYDEN. Thus far in Oregon, where it's most likely to occur, it is in the area surrounding the genome project?

Mr. TIMMINS. I couldn't comment on that.

Chairman WYDEN. Mr. Langeler, any further comments you want to make?

Mr. LANGELER. Only thing I might add on the patent issue is the Patent Office, I believe, is suffering from a more difficult problem than the FDA in the avalanche of technology that is being thrown at it, compared to its resources and expertise level. So what we're seeing happen that is affecting the patent is a fair number of patents being issued that never should have been issued because in fact there is tremendous examples of prior art.

But those things can end up in court for years to prove prior art and I have seen a number of those recently, where even the person who filed the patent will admit prior art, but in the meantime years drag by, approval, even FDA approval is reached, now you have a patent battle which keeps people from bringing product to the market.

So if there is anything to do in the Patent Office in my perspective, it would be make sure they are adequately funded with the kinds of attractive salaries and benefits to get the kind of Ph.D.s in there who actually can go back and research prior art intelligently.

Chairman WYDEN. Congresswoman Furse, any questions?

Ms. FURSE. No, thank you.

Chairman WYDEN. We'll excuse all of you. Thank you and we'll be working closely with you on an issue which I know is pretty much the ball game for biotech. We thank you.

Chairman WYDEN. Our next panel, biotechnology and the environment, is Nan Newell, executive director, Oregon Biotechnology Association; Mr. William Weinstein, executive vice president, Emerging Technologies International; Jerry Yudelson, president, World Envirotech; and Mr. Ken Williamson, director, Training and Technology Transfer at Oregon State.

We welcome all four of you. It is the practice of this subcommittee to swear all witnesses. Do any of you have objections to being sworn as witnesses?

Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. We'll make your remarks a part of the hearing record. We want to thank you. This is an area where my colleague has just done yeoman's work and I know worked very closely with many of you through her tenure in Congress.

Let me also say, Ms. Newell, that it's just great to have you with the Oregon Biotechnology Association, and I don't think it's coincidence that all the new attention for biotech has somehow magically coincided with your departing Washington, DC and coming to Oregon. So we're real glad to have you, and please proceed.

TESTIMONY OF NANETTE NEWELL, EXECUTIVE DIRECTOR, OREGON BIOTECHNOLOGY ASSOCIATION

Ms. NEWELL. Thank you very much. I'm Nanette Newell. I am the executive director of the Oregon Biotechnology Association. I'd first like to thank both of you for having this hearing today, for bringing biotechnology a little more visibility in the State the Oregon. I really appreciate both your support.

This morning's panel is on environmental technology, this particular panel, and just as a way of background, I was the founder of a company called EnSys Environmental, which is located in North Carolina, in 1986. That company is now publicly traded. It's a company that took some technology that was very prevalent in the medical diagnostic communities that biotechnology had developed in the mid-1980's, and now is using this technology instead of detecting medical diseases to detect environmental toxins. So I've been very interested in this field for a long time.

I've also spent some time studying the usefulness of microorganisms in plants to clean up toxic waste and have also spent some time looking at the compost technology. So it's a field that's very much of interest to me.

Congressman Wyden started the hearing with a definition of biotechnology. I think it's worth repeating, because a lot of people have said what does it mean to have biotechnology in the environment? I define it as the use of organisms to do useful things. So this would include both—in case of the environment, both microorganisms, which I think we hear quite a bit about, but also potentially the use of plants and trees to be planted on toxic waste sites and so absorb and degrade toxic chemicals.

It's also the use of organisms not only for toxic chemicals, but also for problems that we might have in our environment with nontoxic chemicals or nontoxic issues such as just standard biological waste such as composting. So environmental biotechnology I feel covers a much broader field than we might often hear about.

It's not only bioremediation of waste that's already out there, but also the treatment of waste before it leaves the factory. So there's a number of different areas that this particular topic can cover.

I want to talk about three particular areas, the first of which is the funding situation. This is not access to capital for companies, but this is funding for basic science. One of the reasons that the health side of biotechnology has become so prevalent is because we've—we as a society over many, many years have chosen to fund health-related basic science and that funding that is done at the NIH and through the NIH has produced our very, very successful biotechnology industry. It is that NIH funding that has made it more successful in this country than in other countries.

We had funding that was similar in terms of peer review and so on in the environmental area for biotechnology not only in terms of remediation, but also in terms of energy production, in the

Carter administration. During the first part of the Reagan administration, all of that funding was cut out and there never really has been a restoration of any basic science funding for environmental applications to biotechnology.

I think that we all know that many of these techniques are very new and that our exploration of molecular biology and organisms is very new and until we really understand how organisms actually can degrade waste, we won't be able to use the vast amount of technology we have at our fingertips to actually improve the organisms that are already out there.

As things are currently done, people are using organisms that are already present in the environment and we in the biotechnology community, we believe that we can dramatically improve on those organisms if we had some understanding of the basic science of them.

Now, you might ask, if this is so important, why has industry not actually funded some of this basic science? First of all, industry tends not to fund basic science to begin with, but the second point is that the regulatory area, especially as it resides within the EPA, has been moving more glacially than that at the FDA, if that's at all possible.

The regs for the deliberate introduction of genetically engineered organisms into the environment were first drafted in the early 1980's when I was in Washington and I helped work on those. They have not changed one bit since that time. We now have 15 years' worth of environmental data to suggest that genetically engineered organisms, at least those in certain classes, are not at all detrimental in environmental situations, yet the EPA still does its analysis on a case-by-case basis and it is extraordinarily slow. It is probably the lack of clarity and the inability of the EPA to kind of come up to date with their regulations that has kept some industry money and some venture capital money out of this particular field.

The third area I want to talk about is what I call the, quote, unquote, approval process for new technologies within EPA. Again, as bad as the FDA may be, as was discussed in our earlier panel, at least within the FDA what the approval process is, you know exactly what kinds of documents you need to submit, and you know that even after a length of time, you will have a yes or a no.

Well, it turns out that the major environmental consulting firms will not use new technology unless it is listed as a method approved, in quotes, by the EPA. Yet there is no formal approval process. If you go to the EPA, they say there is no approval process, can you go out and sell your technology to anyone you want. But in fact unless it's listed in an EPA methods book, it is very, very difficult to get your technology into the marketplace.

It's especially difficult for small companies who really don't understand who to go talk to within the EPA, and how to kind of weave your way through the EPA in order to get your technology listed in these methods books. So I'd just like to suggest three things that come out of the three issues I've just discussed.

The first is funding basic science. We are very, very big supporters of the concept of the National Institute for the Environment, if in fact it's run like NIH with peer review, grant application processes. I think we have found that the peer review system is abso-

lutely the most effective at generating the best basic science that we can do and we suggest that you support the National Institute for the Environment if in fact it has the same kinds of granting processes that NIH has.

The EPA has also put quite a bit of funding into biotechnology, they put it all into risk assessment. They have found no risk so far, as far as we've been able to tell, and we would suggest that the EPA take some of that funding that they're using for risk assessment and actually use it to help determine the beneficial uses of organisms in the environment. Finally, DOE, who is also spending quite a bit of money now on remediation, could spend some of that money on bioremediation and biotechnology.

The second suggestion is that the regulatory environment for genetically engineered organisms be clarified and be brought up to date. I think that this would help very much to get more industry people involved in helping fund some of this, some of this molecular biology of environmental biotechnology.

The third suggestion is to somehow develop better ways for small companies to get their technologies into the EPA, to get them tested, and to get them listed assay proved methods in the EPA handbooks.

With that, I will turn the panel over to the people who actually do this work on a day-to-day basis so they can discuss more specific applications of this technology.

Thank you very much.

Chairman WYDEN. Well, thank you. Excellent suggestions, Ms. Newell. We'll have some follow-up here in a few moments.

[Ms. Newell's statement may be found in the appendix.]

Chairman WYDEN. Let's go to Mr. Weinstein.

TESTIMONY OF WILLIAM WEINSTEIN, EXECUTIVE VICE PRESIDENT, EMERGING TECHNOLOGIES INTERNATIONAL

Mr. WEINSTEIN. Thank you very much. I want to thank you, Congressman Wyden and Congresswoman Furse——

Chairman WYDEN. I'm going to ask you, Mr. Weinstein, too, as well, to push that mike a little closer to you. Thanks.

Mr. WEINSTEIN. I also like to make a comment that you mentioned about Congresswoman Furse doing the yeoman's job in this area. I think it's gone beyond that. She has been really what I call riding the white horse for people like myself in the environmental industry, and we all recognize that.

I'd first like to start by talking a little bit about Emerging Technologies, which is my company. We're a biotechnology corporation which was founded with a commitment to provide quality environmental remediation services, employing leading edge technologies, and cost-effective solutions. We have brought together a group of highly qualified and experienced biotechnology professionals to bring to closure specific environmental problems. We offer leading edge technologies in the field of bioremediation, including but not limited to in situ and ex-situ remediation for a wide range of contaminants ranging from diesel fuel, creosotes and pentachlorophenol.

We also have garnered DCR technologies which include a group of patented waste treatment processes developed in Germany.

These processes are used for stabilization of organic and inorganic waste contaminants, including treatment of PCP contaminated soils and sludges.

First, I want to go back to our mission. ETI began its mission in Alaska. I spent the decade in Alaska before I moved to Portland 3 years ago. I was the city manager in Cordova, Alaska, during the *Exxon Valdez* oil spill, and we began our quest after the *Exxon Valdez* because there was nothing in this country that could deal with a spill of that magnitude to clean up a spill of that magnitude, which prompted us to go worldwide looking, searching for technology that would be involved in that area.

Alaska always enjoyed a unique relationship with Russia. We had been bringing delegations with Russia long before the lower 48 was involved in that. We had heard of some scientists in Russia that had developed this type of technology which was a biological way to clean up contaminated soils and waters. We brought them to Alaska. We were in research and development for 18 months. The technology proved out and we moved to Portland to commercialize and market this technology.

We have developed a tremendous relationship with the Russian Academy of Sciences and various academic centers in Russia, and we have become a clearinghouse in environmental science almost for technologies coming from Russia to the United States.

I think biotechnology is the most cost effective remedy available to the environmental community for cleanup of toxic organic contaminants that threaten human populations and ecological receptors. Unfortunately for Americans in general, the use of biotechnology in the cleanup of hazardous materials is underutilized.

I'd like to make three salient points here: One, innovative technology comes from small businesses; number two, the Department of Energy and the Department of Defense sites are monopolized by large consulting firms; three, the very technology that could solve these complex problems on DOE and DOD sites are not allowed to take its place in the market.

How do we solve this problem? Well, I want to offer at least one solution to this problem. Recently I've been involved with the putting together a proposal with a colleague of mine that was submitted through the Department of Economic Development at the State level.

President Clinton had set forth an initiative which I think you probably both are aware of through the EPA allocating $50 million for innovative technologies in the export and transfer of these technologies outside the United States. We have successfully put this proposal in and garnered both of your support and the rest of congressional support in the State of Oregon.

I feel that this type of Center of Excellence that we have recommended would be to test these technologies, innovative technologies, and facilitate the transfer and export of these technologies as it would create economic development. We found this to be an expeditious way and cost-effective way to solve a wide range of environmental problems.

I would urge the continuing support of this proposal and this center because I see it as a nucleus to provide the future for biotechnology in the environmental industry.

In addition to that, in today's Journal of Commerce, I think it mentions the Center of Excellence along with some information about this hearing. I will be expeditious now and finish my talk here and thank you.

Chairman WYDEN. Thank you very much. Excellent suggestions and comments, and we'll follow up here in just a moment.

[Mr. Weinstein's statement may be found in the appendix.]

Chairman WYDEN. Let's go now to Mr. Ken Williamson.

TESTIMONY OF KEN WILLIAMSON, DIRECTOR, TRAINING AND TECHNOLOGY TRANSFER, WESTERN REGIONAL HAZARDOUS SUBSTANCE RESEARCH CENTER, OREGON STATE UNIVERSITY

Mr. WILLIAMSON. Again, I would like to thank Congressman Wyden and Congresswoman Furse for this invitation to address the issue of probable encouragement of biotechnology. It's a pleasure to see your interest in this area.

The portion of biotechnology field which I am particularly knowledgeable is related to the use of microorganisms to treat hazardous waste. I serve as the associate director of the Western Region Hazardous Substance Research Center. This is one of the five EPA research centers devoted to research related to Superfund site remediation.

The Western Center, which is a consortium between Stanford and Oregon State, has as its primary mission the development of technologies to treat hazardous waste in place or in situ. Some 80 percent of our research funding is directed toward the use of bioremediation. Our hope is to use bioremediation to conduct cheaper and more effective treatment than is offered by other physical and chemical methods.

This is an exciting time for bioremediation. The concerted effort over the last 10 years by a large number of university laboratories are producing definitive results that can now be taken to the field. I would like to list some examples.

In the Western Region Center, Dr. Perry McCarty and his colleagues at Stanford have now optimized the bioremediation process for the treatment of chlorinated sulfates like trichloroethene, or what is known as TCE. TCE is one of the most prevalent chemicals at over 2,000 Superfund sites in the United States It is also a known carcinogen. This process involves the growth of organisms responsible for the degradated reaction by injecting compounds like phenol or toluene, with subsequent removals of the TCE to levels that meet drinking water standards. This is an amazing feat. The drinking water standard of TCE is 4 micrograms per liter. This winter, this process will be tested on a full-scale basis at Edwards Air Force Base on a TCE plume remaining from practices of improper chemical disposal.

Other researchers such as Dr. Jim Gossett at Cornell has found other organisms that can degrade TCE, under anaerobic conditions. This bioremediation process holds a great potential for application to sites with very high TCE levels often in the hundred to a thousand milligram liter range. This also will be useful at sites where it is not feasible to conduct technologies of bioremediation and we will have to depend on natural processes to degrade the toxicants.

Also within the Western Center, Dr. Morrie Craig and myself have clearly demonstrated the ability of rumen organisms to anaerobically degrade trinitrotoluene, or TNT. TNT presently contaminates over a thousand military sites across the United States The estimated cost of remediation is about $1.5 million. These organisms that we use are capable of complete degradation of TNT to harmless products of carbon dioxide, water, and ammonia.

Dr. Sandra Woods at Oregon State University has developed methods to treat chlorinated aromatic compounds such as pentachlorophenol. There are literally hundreds of wood treating sites across the Pacific Northwest that are contaminated with pentachlorophenol. We are presently using this process in a site here in Portland for the Oregon Department of Transportation to treat contaminated soils with various herbicides. It is estimated that our method will save the Oregon Department of Transportation about $2 million in treatment costs.

Dr. Louis Sinfrini at the Western Center has developed a process to remove chlorinated compounds and it is now being applied at the Hanford facility. The testing alone is very expensive—in excess of a million dollars for this single project. These results are encouraging and can be even considered to be spectacular.

Less than 15 years ago, it was commonly believed that bacteria were unable to degrade any of the compounds that I've mentioned today. We now know much more about the application of biotechnology to the bioremediation field, but there is still much to learn.

What are some of the important research problems that we now face? First, bioremediation reactions are complex. The reactions often involve complex interactions of compounds and organisms feed on and the compounds the organisms use for exploration. The compounds we add and the mixture of compounds present at contaminated sites often result in chemical reactions that are totally unexpected.

Two, bioremediation requires delivery of large quantities of chemicals to a subsurface. The technologies to supply chemicals in appropriate quantities and concentrations to contaminated soils and aquifers is essential. After delivery, the compounds must be effectively mixed over large areas. Presently, we just do not have effective methods to accomplish these requirements. This also, I see, is the most promising area which small companies could operate in bioremediation field.

Third, the remaining concentrations in the contaminants after bioremediation are hard to predict. Regulations often require that we predict the concentrations after treating or that the end constellations will be below drinking water standards. With bioremediation, we often do not know what such values will be, and as a result, the application of bioremediation is often not chosen.

So what can the Federal Government do to support this biotechnology? First, it must be clearly said that whatever support the Federal Government gives to the bioremediation research at this time will be a good investment. The DOD and DOE cleanup estimates alone run over a hundred billion dollars for hazardous waste sites.

We now know that many of these sites will be bioremediated, or they won't be remediated at all. We just will not be able to afford all of the technologies. This is a technology for which one of the most important users will be the variety of Federal agencies. More support, however, is needed in this area.

Many advancements are now ready for pilot scale or field scale testing. However, the cost of such operations are large. It's not unusual to spend over a million dollars on a single field test of a new technology in bioremediation.

Some specific examples of additional Federal support need to be noted. First, the five hazardous substance research centers funded through the EPA by Superfund have always been underfunded. At a million dollars per year, these centers can only support about six research projects per center per year. This is such an underutilization of the immense expertise present in each of these centers. It would simply be cost effective to fund the hazardous substance research centers at a higher level.

Next, the House of Representatives could restore the funding for the Water Resources Research Institute that was cut from the 1995, 1996 fiscal year by 25 percent. I serve as the director of Oregon's Water Resources Research Institute, and over one half of my research projects are devoted to bioremediation research. Our planned research was to be immediately transferred to an Oregon consulting firm to increase their competitiveness in the national and international markets. Such research will now have to be forgone because of these budget cuts.

Last, as Nan noted, Congress should give serious consideration to the National Institute for the Environment initiative. The support for environmental research has for too long been too little, too fragmented.

Over my 20 years of doing environmental research in this area, I have had funding from over 10 Federal agencies. Such fragmentation results in serious duplication and a lack of comprehensive planning. It is time to consolidate our efforts into one agency that can set environmental research priorities and directions.

Thank you.

Chairman WYDEN. Thank you. Thank you very much, Mr. Williamson. It's a critical area and one that I think has gotten lost with all these agencies and kind of pathways that you find yourself marching through at the Federal level. We'll have some questions in a moment.

[Mr. Williamson's statement may be found in the appendix.]

Chairman WYDEN. Mr. Yudelson, welcome.

TESTIMONY OF JERRY YUDELSON, PRESIDENT, WORLD ENVIROTECH

Mr. YUDELSON. Thank you, Congressman Wyden, Congresswoman Furse. Nice to see you again. Thank you as everyone else has done for shining a spotlight on this area of business that we're all engaged in.

I've given you some extensive prepared testimony with some very specific recommendations and I wanted to take my oral testimony time to give you perhaps a little broader perspective on some of these issues.

I also serve, in addition as president and chairman and CEO of World Envirotech, a company based here in Portland I started about a year ago, specifically to commercialize environmental biotechnology as our charter, if you will. Our first technologic focus is on the air biofiltration, which is the use of filters containing microorganisms that can degrade hazardous contaminants. We have just put our first commercial product on the market. The company has been largely self-funded by myself, and also with the help of some SBIR research from the Air Force. That kind of got us going. We acquired some additional customers as well.

I am an officer and director of the Oregon Environmental Technology Association, so I think I can speak for a lot of the small companies in our industry. I think that this morning I wanted to give you particularly a small business perspective on some of these issues.

We are looking at environmental biotechnology as an industry which we believe within the next 5 to 6 years can offer a billion dollar revenue potential, domestic environmental cleanup markets, with appropriate Federal and State help. Our company projects alone $25 million in sales in the year 1999 as part of our business plan. We are also looking at an industry which I believe can show an export potential of around a billion dollars by the turn of the century. So these are not small numbers and I think they are worthy of your focus.

Obviously, there are a lot of barriers to commercialization. I started about 15 years ago trying to commercialize new technology in the area of renewable energy when I worked with the governor of California at the time. So I have seen this area come and go, the area of trying to reduce barriers to commercialization. I think the previous speakers have touched on what I would consider to be the primary barriers of commercialization of this technology, and that is its credibility.

There is not enough time as a small business to go through 2, 3, or 4 years of research in one site after another to establish the credibility of their technology like biofiltration. We have come up with some marketing programs where I'm basically guaranteeing the results at my own costs. I always figure that's the best way to get somebody's attention. But we do lack, and there is kind of a creditability gap between the kind of good research that Ken Williamson and his people do and the large number of applications which you need to establish the parameters for a technology that might be expected to work in Arizona, Florida, Alaska, and Maine, as well as in Oregon. So we are looking for credibility and there's several different ways that this can be given.

In my prepared remarks, I talk about research support with the SBIR Program on field demonstrations, but I think that the biggest support that you can give is to give some personality to the President's overall commitment to the air environment technology exports, to give some personality to the interest that this administration has in commercializing new technology for domestic applications. Obviously, the personality that makes the most sense to the most people is to get it into use. That involves the Federal budget process.

People have talked about DOE. I believe that right now DOE is about half the Federal market in remediation. I think their budget this year is slightly over $5 billion. I have seen tremendous support at EPA, I have seen good support at the Air Force, some support from the Navy, but I don't see much DOE support for bioremediation or environmental biotechnologies. I think that's an area where, with the current management changes that Secretary O'Leary is giving to the Agency, you have an excellent opportunity to put some pressure on to get people to look in the nonradioactive area of DOE's cleanup, which is about a quarter to a third their total money, to really look at how to clean up the Hanford site with biotechnologies, to look at how to clean up some of these other sites.

I think that as Jerry Langeler and other expresses in the earlier panel, investor interest follows public commitment in many of these areas. The biggest sign of investor interest would be for other agencies to do what EPA did 5 years ago and EPA did declare bioremediation field initiative. They are currently the largest Federal funding I think for bioremediation right now. So other agencies can do, and I discuss a number much ways in my testimony.

I want to deal with two other things very briefly, and then we can answer questions. One is technology certification. I think Nan Newell addressed that issue. There is no real EPA certification of new technologies. In fact, we get our technology in the marketplace by relying as a backup, if you will, on an already certified technology which we'd rather not do.

But I've talked with EPA Region 9 director, I've talked with the scientific people in Region 10. There's no clear process for bringing a technology to EPA, having people look at results and say, yes, this is our best available control technology in this biotech area. It's just too new for them.

Finally, export promotion. Clearly, all of the good things that are in Congresswoman Furse's bill need to be implemented, budgetarily, in terms of personnel. We'd certainly like to see an ability for people working in this area of the country to focus a large amount of their attention on the very promising environmental biotechnologies as part of the export promotion.

So again, we think there is things that both of you can do for us in Washington, at the Department of Commerce, and other agencies to again shine a spotlight on this industry. So that would be my oral testimony. I've given you a lot of specific proposals in the written testimony.

[Mr. Yudelson's statement may be found in the appendix.]

Chairman WYDEN. Thank you. All of you have just been excellent in an enormously important area and it wouldn't be right to let anybody else start except Congresswoman Furse.

Ms. FURSE. Well, thank you. I should of course say that my bill was early on cosponsored by Mr. Wyden and we worked very closely together on this. It makes a huge difference to have a number of people working together to push it.

There are a couple of issues I wanted to ask you, Mr. Weinstein. We have just passed an acquisition reform legislation—I was on that conference committee—which seeks to make it easier for small

companies to work with the Government. I think everybody here on this panel—have helped my thinking of how we needed to do that.

Do you think that if small companies could get together to contract, for instance at Hanford, which is a big concern of mine, I'm on the DOE panel, obviously we all drink the same water, we know that that's a real problem, could you—do you see them working together, smaller companies, to solve what I think is in many ways a cultural problem at Hanford?

Will acquisition reform help you as a company?

Mr. WEINSTEIN. I think acquisition reform will help. I wanted to make a comment, I am glad you brought that up. It's just an important statistic about Hanford. Hanford has caused a great deal of problems for Oregon, the Columbia River, for example.

I don't know if you're aware of this, but only 3 percent of the monies that come to Hanford comes to Oregon businesses, 3 percent. It's ludicrous. I don't mean 3 percent of the contracts, I mean 3 percent of actual dollars. That needs to be changed as rapidly as possible. We have people at Hanford called Repto Corp. and Westinghouse. These are very large consulting firms.

I wanted to make this comment again about consulting firms. This is not necessarily an indictment of them on the one hand, but on the other hand it is, because they are perpetuating the problem we have in the environmental industry because they are spending millions if not billions of dollars and have been on doing studies, feasibility work, to tell you what the problems are, and very little if any money has been spent on actually resolving the problems. The technology that we have is involved in resolving those problems.

I would take you again back to the Center of Excellence that I promoted and is being promoted by the State of Oregon, because if you have a nucleus set up here, then people like Hanford and people across the country and at other places in the world will look at this center and say, here is a center where technology transfer is taking place, innovative technology is being looked at, and you can create this awareness. I think it will be very beneficial in working with a place like Hanford.

I think it's important for the alliance of small businesses and large companies to work together, but we have to pierce this veil somehow with the large consulting firms. I think the Department of Army, for example, acknowledged and Ken Williamson alluded to this situation, there's a tremendous amount of remediation that needs to take place in this country. This perpetuation is still taking place.

We need to take our companies right in the doors with this innovative technology to the appropriate people and move aside from a lot of the bureaucracy, just sit down and make the point not only that we have technology, validated technology. I mean, our company is doing work for Chevron, Texaco, Southern Pacific Transportation Company, and we are being successful in this and this type of word needs to get out, other than our promotion for ourself. But we've got to have the support of Congress and everyone in the State to do that.

Ms. FURSE. Mr. Yudelson, do you think the Federal Government has any particular programs that facilitate export of environmental

technologies and environmental biotechnology? Which are they and who does the best job?

Mr. YUDELSON. I've been subscribing for the past year to the USA's Environmental Partnership, which is a kind of a networking group that puts commerce agents out in various cities in Asia. They have been sourcing all kinds of bid opportunities. But I would say at this point what I have seen come over the fax machine every night, which is four or five nights I get something, is primarily opportunities for large companies and primarily very conventional technologies such as solid waste management, water purification, wastewater management, which are fine opportunities for American companies, I think that's a good program. But there seems to be very little understanding at the agency level.

I think this is run out of Commerce, about technology opportunities in this area. Of course, individuals who are training to be Commerce officers, I don't expect to be technical specialists. So we kind of come back to the need for partnerships such as EPA, Commerce, or other agencies of Commerce having to learn more of our technology, learn more of the opportunities where we might be successful and be able to source those, some of the smaller opportunities for the large number of companies which are not about to get on a plane and fly to Taipei from Portland to look for a bid opportunity just the first time out.

So I have seen that partnership be successful in sourcing opportunities, and good size ones. But they don't work for me, they don't work for this technology at this time. So I think you could do more in that area.

Ms. FURSE. Which I think, just as a comment, leads to the appropriateness of this hearing being in this committee, that there's so much—it sounds like there's so much entrepreneurial work going on and it needs to be in those small companies.

I have other questions but I'll submit those, Mr. Chairman, and just thank you.

[The information may be found in the appendix.]

Chairman WYDEN. Well, thank you for all the work you're doing. I'm anxious to follow up in this area and the other with you.

I think the only one I have, Ms. Newell, what you described about the EPA really sounds, even by Washington, DC standards, to be never-never land. This idea that you put forth—at least the FDA has got an approval process. We don't like it. Congresswoman Furse and I have wrestled with this process for Oregonians all the time.

But what you're saying basically is that it's just sort of, free form at the EPA, that they have no process for new products. Why don't you give us like an example of what the situation is now and what would be helpful for us to try to bring about to change it?

Ms. NEWELL. All right. The example that I am most familiar with is the one that we have when it was at EnSys, a company that I founded. This company was using a technology called amino assay to detect toxic chemicals, which is a very accurate, specific assay that can be done actually in the field in about 15 minutes.

Now, the comparable assay that people were using at the time was to, say, dig up a dirt sample or take a water sample, send it off to the analytical laboratories, where 2 weeks to a month and

$100 to $1,000 dollars later you would have your answer. In that process——

Chairman WYDEN. That's the old assay?

Ms. NEWELL. That's the old assay. But that was the gold standard, that was the assay that was approved by the EPA. We estimated that it took us about three person years to get our assay written into their books. Because—because part of the reason was in fact the assay for pentachlorophenol, which was the first one that we had, was better than the gold standard, it was better than the gas chromatography standard that they were using, and therefore they weren't going to accept the data because it didn't match the data that they had, even though we could go again to even better analytical techniques and prove we were being more accurate than their current gold standard.

It was just as a small company, when you have to kind of sit down with the EPA phone book and figure out who you're going to call to talk to about a brand-new technology, it was just extraordinarily difficult to get to the right people.

Chairman WYDEN. At present, there is no EPA office that deals with giving the green light for these new technologies?

Ms. NEWELL. Well, it's different for different technologies. Second of all, one of the things that happens is that you have to go—the EPA in Washington doesn't necessarily do this. Each of the 10 regional offices has to give the green light, which also makes it very, very difficult for small companies. So there are people who you can go to, but you have to figure out who they are, and then you have to figure out where they are. Then you have to do it region by region. Often also State by State.

Chairman WYDEN. So if you're a small Oregon entrepreneur basically tapping new technology opportunities with EPA, is it at best hit and miss?

Ms. NEWELL. That would be what I would say, yes.

Chairman WYDEN. At best. If you can find the right people and make your way through a 3-year exercise like you all did with your assay——

Ms. NEWELL. Our alternative was to hire regulatory counsel, which we went to Washington and decided to do. We interviewed several firms. The problem was, was that because it was new technology, they didn't know who to go to either. We ended up not doing that and deciding that for the time—the time and money that we had, it was best to do it in-house. I'm not sure that was the right decision in retrospect, but there was really not even regulatory counsel you could hire to do it.

Chairman WYDEN. If your members were willing, I would be very interested in having a paper on the kinds of reforms you would like to see in this area of the EPA. As I say, another part of my life, I sit on the Health and Environment Committee and we got jurisdiction over EPA, and I would very much like to pursue this.

Ms. NEWELL. Well, if my colleagues here would help me out, we would be willing to do that.

[The information may be found in the appendix.]

Chairman WYDEN. Because I think that Congresswoman Furse has really launched this effort with her bill. But clearly now with other agencies we're going to have to bring along.

Ms. NEWELL. It's very unusual for an industry to be coming to you asking for regulations, which I feel is kind of what I'm doing. I don't want to be mistaken and we want to come and say we want to be a regulated industry. But we would very much like to have a clear pathway to go to one place, preferably in Washington, DC, to have a technology looked at and then to have that information spread around the other EPA agencies and the States.

Chairman WYDEN. Let's put it in the context of trying to liberate people rather than to try to pound them into submission with more of the Washington business as usual regulatory operation.

Mr. WILLIAMSON. Could I say something?

Chairman WYDEN. Sure.

Mr. WILLIAMSON. Not to be a grandstander of the EPA, but they do have a Technology Innovation Office that's run by Walt Kovalick that does an excellent——

Chairman WYDEN. Technology Innovation Office, is this one in our region or in DC or——

Mr. WILLIAMSON. It's run in DC, yes. They go to great efforts trying to push along new technologies in the waste remediation field. Not only do they—not only are they willing to look at any new technology, but they're also willing to help people to try to find potential funding that demonstrates such technologies as through the site program.

There is also a National Innovative Technology Testing Center that EPA has funded that you can actually take these technologies to, they will test them. Then they also have a tremendous technology transfer function in which they put these reports into hard copy which you can—anybody can obtain, free. They have an elaborate electronic network which you can access the topics that are available. I think the EPA does a very good job of trying to push these technologies.

Now, the technology that Nan is talking about is especially difficult because it fits into the little teeny corner of new measuring methods. That is very difficult. That one is bogged down immensely in all sorts of scientific approval and statistics and trials and on and on and on. I think that area is very difficult.

The other area that is extremely difficult is the use of bioengineered organisms. That one also gets bogged down, another little corner of EPA. But this sort of thing of just having a new hard technology that you want to use in the remediation field, I think the EPA does a pretty good job.

Chairman WYDEN. Well, I wish to follow this up with all of you and the suggestions. Does this technology office ever come to Oregon and have a program with people like yourselves?

Mr. WILLIAMSON. Walt has come to several conferences that we sponsored. He will go anywhere to tell his story. They've had various meetings at which they've invited various industry representatives from Oregon. I think they do a good job.

Mr. WEINSTEIN. I think that for the most part I agree with Ken. I think that, though, the decentralization of this type of strategy and the regional centers as we're projecting here, Oregon would be a lot more helpful because it's still a tremendous bureaucracy to go take a technology in.

I'd also like to make this comment on the political side, that I'm sure as both of you know, to my knowledge, the former director DEQ is now the number two person at EPA. I'm hoping that this will benefit people of Oregon in some capacity as far as maybe breaking through to get to the appropriate people there.

Chairman WYDEN. We both were very supportive of Mr. Hansen. Now we've got something to take up as soon as he gets his desk dusted off. I'm going to excuse you, but your point, I think, about the decentralization, if you look at the successes that are now coming out of the public policy process at the Federal level, a substantial number of them are building on this decentralization model.

I mean, under Erskine Bowles, for example, the Small Business Administration has gotten a lot of what they used to in Washington, DC, out of Washington, DC, and out around the country. As part of the small business package, I'm in effect advocating the same sort of thing in the export area. As the export programs in this country work great, if you're one of the giants, and Boeing, for example, knows how to use it, we want Boeing to be a success, they're important to our area.

But what we want to do is get a lot of those export functions out of Washington, DC, and around the country. It seems to me you're advocating, Mr. Weinstein, really the same principle in the environmental area. We're going to be anxious to follow along with all of you.

We'll excuse you at this time. Thank you.

Our next panel will deal with the Human Genome Project, extremely important area, federally funded research. Pleased to have Dr. Maureen Hoatlin, Oregon Health Sciences; Dr. Ry Meeks-Wagner, University of Oregon; and Dr. Dennis Borden, assistant vice president of Research Administration, Oregon Health Sciences.

It is, folks, the practice of this subcommittee to swear all witnesses. Do any of you have any objection to being sworn?

Please rise and raise your hand.

[Witnesses sworn].

Chairman WYDEN. All right. We'll make your prepared remarks a part of our record and very much appreciate your coming and feel that this is really one of the most exciting areas of biotechnology.

Dr. Hoatlin, why don't you begin.

TESTIMONY OF MAUREEN HOATLIN, OREGON HEALTH SCIENCES UNIVERSITY

Ms. HOATLIN. My name is Maureen Hoatlin. I'm an assistant professor of Oregon Health Sciences University, and I work in the Division of Hematology and Oncology. I'd like to thank you for inviting me here today and express my wishes of how biotechnology can be developed in Oregon. It's an issue I am very interested in, especially as it relates to the Human Genome Project.

In my research that I do, I'm interested in understanding the molecular mechanisms of hematopoietic diseases. Those are diseases that affect the form and elements of the blood. I am very interested in developing gene therapy here at Oregon Health Sciences University. General therapy is a new technique that shows great promise for the treatment of genetic diseases, as well as other diseases, such as cardiovascular disease, AIDS and cancer.

A very general definition of gene therapy is the transfer of new genetic material to an individual with resulting therapeutic effects. In particular, my focus right now in my research is Fanconi anemia, which is a very rare fatal children's disease. A large NIH grant has been recently obtained by Oregon Health Sciences University to support the work of the many scientists and physician teams that are working to understand the mechanisms of this disease and to bring about a cure for Fanconi anemia.

What I'm working on right now is trying to establish a laboratory that will be a source for OHSU researchers for gene therapy vectors.

Now, a gene therapy vector is a virus that is engineered to enable the transfer of this new genetic material to the cells of an individual you'd like to treat. Not only would this be for Fanconi anemia, but for use in treatment of other diseases as well. This laboratory is just one example of a laboratory that can be viewed as a hybrid between an academic research laboratory and a private biotechnology research and development lab.

I've had professional experience in academics as well as private industry, and I feel very strongly that separation of academics and industry is no longer applicable for the revolution in biomedicine that we are now entering in. We need to combine the strengths of both academic and biotechnology industry if we're to take advantage of this tremendous technology we have right now.

I'd just like to give you an example in gene therapy for what I'm talking about here. When I'm interested in a gene that causes a disease, first this gene must be cloned, has to be discovered. The normal gene must be isolated and placed into the suitable vector, such as the retroviral vector that I mentioned, and then the vector bearing the correct gene must be produced according to strict guidelines for safety and efficacy. This vector is then administered to a patient in a clinical setting, and then the corrected cells from a patient must be followed over time to ensure that the transferred gene is still functioning.

I think you can see from this concrete example that an academic lab would have difficulty funding the expensive production facility required to make and test vectors. We're talking $2 to $10 million for a GMP, a good manufacturing practice facility.

At the same time, research in gene discovery, the basic research involved in transplant biology, a critical issue right now, and the post-treatment patient follow-up would be difficult to do in industry.

There is an additional reason that an academic private hybrid laboratory would be ideal. Gene therapy vectors for the treatment of diseases of low incidence, such as Fanconi anemia, could be developed by academic researchers and produced by the private lab, by the private lab having other concerns, and this orphan disease, for example, a vector could be produced in small batches. In this way, it would be economically feasible to treat diseases affecting a small number of patients.

In the past for gene therapy, there have been agreements between industry and academic labs and they've been called CRADA's, cooperative research and development agreements. They were established by the Federal transfer—or Technology Transfer

Act of 1986. In this agreement, the private company serves as the active laboratory for the academic lab and the pooled resources tend to strengthen the research project. This is only one possible mechanism for encouraging biotechnology growth in Oregon.

I'd like to emphasize to the panel some of my personal comments.

I think this is the best possible time to be studying biomedicine. The technology for gene discovery and transfer is in place, or it's developing very rapidly. This is the payoff for all the past years—I think we've heard from other panels, too—of all the years that NIH has been funding biomedical research. I believe that the cost of treating patients in gene therapy will be offset by the gain in quality of life for these individuals and the reduced health care that these patients will require over the long run.

I cannot overemphasize how much I think Oregon will benefit from an increased commitment to genetic research. Discovery of new disease genes, methods of treatment and diagnosis, would likely develop biotech industry in Oregon, as well as attract grant money to expand basic research in the academic setting.

Thanks.

Chairman WYDEN. Dr. Hoatlin, thank you. We'll have some questions in a moment.

[Ms. Hoatlin's statement may be found in the appendix.]

Chairman WYDEN. Dr. Wagner.

TESTIMONY OF D. RY MEEKS-WAGNER, UNIVERSITY OF OREGON

Mr. MEEKS-WAGNER. Congressman Wyden, Congresswoman Furse, thank you for an opportunity to——

Chairman WYDEN. We've got again scientists with really soft voices.

Mr. MEEKS-WAGNER. I'm recovering here, I'll try better.

Thank you for the opportunity to enthusiastically support the goal of establishing and promoting both academic and private biotechnology research in the genome science in the State of Oregon.

In her acceptance of the Nobel Prize of medicine in 1984, Dr. Barbara McClintock, a geneticist who clearly could see well ahead of her peers, stated that the analysis of gnomes was to be one of the most important contributions to modern biology. Several years later, the groundwork was laid for the human genome project, the aim of which was a complete understanding of the human genetic code by the year 2005. This was to be the greatest unified scientific undertaking ever attempted and would clearly require the development of new technologies hand in hand with data collection.

In just 5 short years, the field of genomics has in fact gone much further than anyone, except perhaps McClintock, could have imagined. Each week, if not several times per week, we read in the newspapers of the identification of genes that control human development and disease susceptibility. In the last 2 weeks, we have read of the identification of a breast cancer susceptibility gene, of a gene that is involved in the expression of dyslexia, and a gene that may influence the expression of violent behavior.

This is only the tip of an enormous iceberg of information. We're on the threshold of a revolution, and the next decade in genomics will provide amazing insights into human growth, development and

behavior; into ways to improve our agricultural crops and livestock; and into ways to monitor and conserve our environment.

The field of genomics is just beginning to make major contributions to improving our world in a wide variety of areas, including medicine, psychology, sociology, agriculture, forestry and fisheries. I strongly support the development of genomics in the State of Oregon, for I believe Oregon is in a unique position to both contribute and benefit from genome research.

We have the academic environments required to foster creative investigating in genomics. For example, the University of Oregon is ranked in the top 10 in the United States in biological sciences, including public and private institutions, based on the scientific impact of research published in peer reviewed journals; Oregon Health Sciences University is ranked among one of the top medical schools in the United States; and Oregon State University has some of the top programs in the United States in agriculture, forestry and fisheries. Furthermore, as we've heard previously, Oregon is making excellent strides in developing first-rate private biotechnology companies.

Genomics, and this is really the point that I'm trying to bring to you today, is that genomics has spread beyond the human genome project. I think this provides a unique opportunity for Oregon. Two examples of this can be found in my own research.

The first example is my laboratory's analysis of the genetic control of flowering in higher plants. We have identified several key genes that appear to connect the internal biological clock to the process of flower formation. At present, the best model systems for understanding our biological clocks happen to be in organisms such as plants and fungi. However, given the amazing degree of conservation of biological mechanisms, it's expected that the analysis of the biological clock in these organisms will be directly applicable to the clock in humans and should lead to an understanding of treatments for many human physiological disorders relating to the function of the human clock.

In 1990, the community of scientists who work on this model plants, Arabidopsis, set out on its own genome project to facilitate the understanding of the genes that control plant growth and development, disease resistance and plant responses to the environment. Given that this genome project is carried out in individual labs around the world without assistance from what I'll refer to as genome centers, we are making steady but only moderate progress.

I can submit to you the third-year report from this multinational effort to work on the genome around the world.

[The information may be found in the appendix.]

Ms. MEEKS-WAGNER. The second area of research, the dog genome project, is one that I've recently joined in calculation with colleagues at the University of California, Berkeley, the Fred Hutchinson Cancer Research Center in Seattle, and a colleague at the University of Oregon. The project is aimed at using the domestic dog as a model for understanding the genetic control of animal development and behavior. The dog provides an excellent source of differences in size, shape and behavior.

In theory, the genes responsible for these traits can be identified and isolated using genome analysis. My particular interest in this

work is the identification of the genetic basis of complex behavior such as attention span, avoidance and aggression. Many domestic dog breeds display very large differences in these behaviors. Genomics should allow the genes that control these behaviors to be isolated and studied in a fairly rapid manner.

Again, given the large degree of genetic conservation between mammals, many of the genes that control these behaviors are likely to also influence human behavior. Thus our understanding of these traits should lead directly to the development of treatments and therapies for human conditions. However, in order for the benefits of the dog genome project to be realized in a timely manner, we need the support of a genome center.

When the human genome project was initiated, several organisms were designated as models for developing the technology and biological basis for human genomics. This group of a few organisms, yeast, a nematode known as C. elegans, fruit fly, mouse and humans, is now obsolete in terms of the potential impact that genomics can have on human health.

For example, genome analysis in other organisms is suffering due to the exclusion from this list, and yet there are clear implications for benefits to humans from such research. Plant genomics can lead to more direct and better strategies for more crop improvement; cattle genomics can lead to improved breeding for milk and meat production, as well as disease resistance; and, for example, dog genomics can lead to an understanding of human development and behavior and possible to obtain by limiting research only to humans.

I believe that the exclusion of those organisms from the current genome budget is simply a reflection that no one really could have guessed the tremendous impact genomics would have on health and agricultural related sciences. Now is the time to correct this situation.

Given the strength of the academic institutions and the benefits of residing Oregon, I expect the biotechnology firms will find Oregon a good place for business. Genomics is a field that will spark the innovation of an amazing number of new biotechnologies, but what is needed is a mechanism to first jump start the genome research initiatives at Oregon's universities. By building upon the already excellent programs that exist at the University of Oregon, Oregon Health Sciences University and Oregon State University, collaborations with private businesses will be fostered, and this, in turn, should lead to the development of new biotechnology firms within the Eugene-Corvallis-Portland area. This is exactly how public private sector biotechnology collaborations have evolved in other academic centers such as the Seattle-Takoma-Everett area, the San Diego area and the Boulder-Denver area, just to name a few.

In order to continue existing lines of research and to develop now research directions, it is essential that several genome research centers be created right here in Oregon. I imagine that these would operate as core facilities that would serve as a basis for genomics research and would provide many aspects of genome analysis, including the robotics needed to efficiently carry out genome research. The researchers in our State and other northwestern states

would clearly benefit. One aspect of such centers is that funds should be earmarked for aiding the development of new genome research projects in addition to the human genome project.

I believe that it is essential for Oregon universities to become active players in the field of genomics. The universities are, without question, the ground level, the seeds of inspiration, for future progress in this area. The creation of several genome research centers would, of course, need to be done in conjunction with adding new faculty positions at the host institutions. Once this is done, there would be the ability to attract private interests that I think would be eager to take advantage of the core facilities, as well as the expertise at the universities.

Establishing genome research centers would benefit both the citizens of the United States and the citizens of Oregon. There are many reasons for establishing these centers in Oregon. In addition to creating a new employment base in biotechnology, the citizens of Oregon would benefit by having close at hand the resources to address many local, State and regional issues that genomics impacts. These issues range from new methods of diagnostics and therapy for human illnesses and abnormalities, to discovering information related to agriculture, forestry and fisheries improvement and conservation.

At present, such issues cannot be addressed efficiently by the research and services within the State of Oregon. We're fast becoming a State dependent upon our neighbors to provide what should be basic services and product design capability. The time to change this is now. In a few years, we will be so far behind that we will not be able to participate in what is perhaps the greatest improvement in the human condition in modern times.

I'd like to leave you with a thought by another scientist and citizen who profoundly changed our world. Albert Einstein once noted that, and this is a quote, "People love chopping wood. In this activity, one immediately sees results." I put forth to you that people will love genomics, for they are immediately seeing the results of this investment and they sense that it will make the world a better place to live.

I thank you for your consideration.

Chairman WYDEN. Thank you, and a very helpful statement. We'll have some questions in just a quick moment.

[Ms. Meeks-Wagner's statement may be found in the appendix.]

Chairman WYDEN. Dr. Borden, welcome.

TESTIMONY OF DENNIS BORDEN, ASSISTANT VICE PRESIDENT OF RESEARCH ADMINISTRATION, OREGON HEALTH SCIENCES UNIVERSITY

Mr. BORDEN. Thank you very much. Good morning, Congressman Wyden, Congresswoman Furse, excuse me. I'll try to keep my remarks brief. Which are that I'd like to speak first on the issue of funding.

My colleagues in the laboratory would suggest that we ask for the entire Federal budget for two or three decades——

Chairman WYDEN. Transfer the whole Human Genome Project to Portland.

Mr. BORDEN. Not only the human genome project, but the entire rest of it as well.

I'd like to suggest that we need to concentrate on another area which is much smaller than that, and my concern is that of the levels of funding at national agencies when we are funding projects that are only the most illustrious, only the 10 to 12 percentile of quality, and the impact that that has on people choosing science as a career.

I think that we truly, as a matter of public policy, are dissuading a lot of people not to want to enter into the process of doing science, when in fact the levels of funding are so stringent as they currently are. I think that we need to give some type of lift to the young people entering into the field of doing science by if not enlarging the funding levels, which may in fact be a very difficult thing given all the competing priorities, is that we need to establish some additional programs that will encourage young people to in fact become a part of the process.

It was recently published that for the NIH that the funding—the age at funding for the first investigative awarding, so-called RO1 award, has now risen to 37 years of aiming. That limits the productive life that a scientist is likely to have when in fact they do not gain independence until that late in their careers.

So I would suggest to our Representatives that methodologies are needed to involve younger investigators into the process more quickly. We need surer funding cycles. We may perhaps need special awards. We may need lower levels of awards to encourage them, but there must be methodologies devised to get our younger people involved in this process sooner.

It's been alluded to by various people speaking today about the issue of bioethics, but no one has said anything directly to the subject. The dilemmas posed by gene transfer, the dilemmas posed by the use of transgenic organisms, are almost beyond comprehension, because we haven't really had the public discussion I think that is required.

When we look at the concerns of organizations that have nothing to do with science, the insurance industry, the banking industry, Government in general, who will use the works of these people as a means of establishing their own industrial standards, I think that it is imperative that we in fact put resources into some type of Center for Bioethics, that that should become a national debate at the highest level with a considerable level of funding given to that.

I think that this is critically important. We cannot allow gene transfer to which they are. There are just too many individuals who have important aspects of their life to gain from the concepts that can be gained from gene transfer.

The last subject I'd like to bring to your attention is the relationship between universities and academia and the Government and the biotechnology industry. Only rarely do one of our investigators have an idea that truly has commercial potential. The number of dollars that industries bring to the table for universities is truly trivial. I mean, we can barely fund a technology transfer operation. Yet these types of operations are perceived as greed on the part of

universities in terms of we wanted to get rich by, in fact, giving ideas to biotechnology.

I think that while there clearly are aberrations in the environment, is that universities are not going to become rich on the fruits of their biotechnologic innovations. In fact, Oregon Health Sciences University, with its first prospect at making serious money perhaps in a new spin-off company, has decided to dedicate its profits as they are truly developed into graduate education and something that was alluded to by Mr. Langeler earlier this morning, and that's prototype development.

I think that that's something I think that our representatives need to consider, is that perhaps there is a need for a program between small business innovation grants and technology transfer research grants and basic research grants for prototype. I think that there may be a significant need to move the development of technology another step up within universities, because private business is not going to take them at the stages that they are, so that we have more resources brought to bear on that.

The last point that I would like to make to you this morning is that I am very much committed to Congressman Wyden's concept of the public in fact benefiting from the investment that it has made in these technologies. I think that that's absolutely important to assure that we are in fact being good stewards of these kinds of funds.

I think that there are a variety of methods that either would replace or support price capping on the development of new commercial entities that should be given consideration. Whether these be considered special taxes or a sharing of royalties or a variety of other potentials, I think that they need to be looked at for what they would bring back into the public coffers in support of what has been done with public funding. I am convinced that that would be at the expense of universities, but I think that that's something that has to in fact be considered.

With that, I'll end my remarks.

[Mr. Borden's statement may be found in the appendix.]

Chairman WYDEN. Very good. All excellent presentations.

Let me recognize my colleague to start.

Ms. FURSE. Well, I did a lot of homework and my staff did on this issue. We developed six very insightful questions. You've answered every one of them in your testimony. I can't tell you how I appreciate that.

I have two comments, Mr. Chairman. One is, this issue affects us in so many ways. As you were speaking, I thought of agriculture, which effects me, diabetes which affects my family. I think that what your testimony will put forward was that this is something that we all had better get knowledgeable about, because it does affect our lives in great ways.

Then on the issue of priorities, I think, Dr. Borden, you struck a real note for me. The priorities of education, I was reading the other day that we spend more money on Army bands than we do on the whole arts budget for the Federal Government. I would imagine that probably the Army bands are probably closer to what we spend maybe on genetic investigation.

I think you're absolutely right to draw our attention to that, that we really are in the business of priorities. The priorities of education, I think every panel here has spoken very clearly to but I think you in particular.

I do want to thank you, Mr. Chairman. I think this was wonderful hearing and I think each and every panel brought tremendous attention to a very, very exciting but also I think something that says we've got to get going soon, got to be putting our attention here, this is cutting edge and you were right to be worried that we're in the cutting edge and keep there is very important moo to me.

I want to work with you, Mr. Chairman, as we continue on this issue.

Thank you.

Chairman WYDEN. Well, I thank my colleague. I think this is an especially important panel and look forward to getting you on the Appropriations Committee and then we can talk about some of these questions of Federal funding for genome project in Oregon.

I think the one I wanted to start with that was really troubling to me, Dr. Wagner, is you made mention of the fact that other States were moving ahead with respect to genomics. You were concerned that Oregon, I think your words were Oregon was going to wither if we didn't take steps now to catch up.

What are these other States doing or being successful at that Oregon is not doing and not being successful at with respect to the Federal funds and this 15-year effort the Federal Government has launched in genomics?

Mr. MEEKS-WAGNER. I think that to answer your question honestly at first, and then give you some more ideas, it's not so much what the Federal Government has or has not done or the State of Oregon has or has not done with Federal funds. It is what the State of Oregon has done to higher education in the State of Oregon. The centers that are—while we have an amazingly good reputation and outstanding group of faculty in higher education, other States have invested in that in a way that has allowed centers of excellence to develop around them.

For example, probably the closest to home initiative that you could see would be the Boulder, Colorado, University of Colorado, very similar situation to Eugene, somewhat distant from Denver. They have doubled the size of their institution's molecular and cellular development biology in the last 6 years, primarily focused it on bringing in new faculty in genome work and supporting that in a very major way.

That's something we have not been able to do here. The projects are largely developing in areas where there are genome centers related to the human genome center, the DOD projects which are becoming involved in was initiated at U.C. Berkeley in collaboration with the Lawrence Berkeley Laboratory Human Genome Center.

The initiator of the DOD project was until this year the director of that center, was able to take advantage of that. Those are the sorts of things that I think we need a jump start on here to—from the Federal Government, and to also work at the State level to have this happening.

Chairman WYDEN. But it would be your thesis that even if the two of us and our congressional delegation can get a stronger base of support at the Federal level, if we don't see the support coming from higher ed, we'll still have trouble competing with other States; is that right?

Mr. MEEKS-WAGNER. I think that's very true. I think as I said, there needs to be also an increase in faculty appointments that would go along with these building of these centers.

Chairman WYDEN. Now, Dr. Hoatlin, you're a genuine regulation scientist. You're doing work in the anemia field. What does the Human Genome Project, the federally funded project, mean in terms of your research?

Ms. HOATLIN. Well, my focus is trying to cure the diseases by using gene therapy. If I don't have the normal gene, I can't do that. So the genome project is spewing diseases out and diseased genes are just coming out every week.

As Dr. Wagner just pointed out, we read in the paper almost daily about a new gene, breast cancer gene, dyslexia gene, schizophrenia linkage. There's just no end to the number of genes that are being discovered through the genome project that can then be studied and perhaps it might be useful to have gene therapy for those. So I think it's critical, the human genome project is critical to any sort of disease treatment.

Chairman WYDEN. Presumably, if you could get more of this information and access to this kind of work, presumably it would speed up what you're doing.

Ms. HOATLIN. Yes. Right. I'd like to amplify a little bit, just for my perspective, what Dr. Wagner said. I am trying to set up a core facilities that he mentioned for gene therapy. I have, in the process of figuring out how to do this, have talked to about I think four different States.

I just visited U.C. San Diego on Friday to understand how they were funding this. It's very interesting. Most of the States I've talked to—Florida, University of Florida Gainesville, University of Michigan, University of Iowa—the State has put tremendous support to fund buildings and——

Chairman WYDEN. Tell me, this was something I could not figure out as I looked at the various criteria for funding projects. Are Federal funds under the genome project allowed to be used for core facilities around the country?

Ms. HOATLIN. Well, I think this is one of the problems we're struggling with right now, how are we going to fund the core facilities? However, at Oregon Health Sciences University, there is a—it's possible that we can get a cancer center fund to fund core facilities. But some of the—some of the core facilities actually have—what you're making is a product almost. I mean, I'm going to be making viruses to correct disease.

Well, this isn't necessarily fundable through NIH directly. So it—that's why I was mentioning that what we need is a hybrid laboratory, because—and you can't really——

Chairman WYDEN. But would the funds from this project be allowed to be used for one of these hybrid laboratories? That's what I am trying to drive at. Because I am concerned, one of the first kind of thresholds that brought us to this issue was a concern that

Oregon wasn't getting a fair shake in terms of this important research, important Federal research dollar, and the people like yourselves on the front lines could do a lot better with these skill-scarce resources if you were given them. I'm curious about whether Federal dollars can be used for the core facilities that you want.

Ms. HOATLIN. This is what I'm doing spending my time doing right now, instead of doing research. I am trying to hustle for money. I am trying to figure out where the money is going to come from so I can continue doing my research. I don't know the answer to that question yet, but that's what I'm spending this enormous amount of energy doing.

Chairman WYDEN. Even if Oregon then didn't get money for a core facility, it could get money to do some of the research that you are doing, thereby freeing up your time?

Ms. HOATLIN. Yes.

Mr. MEEKS-WAGNER. If I may comment on this for a moment.

Chairman WYDEN. Please.

Mr. MEEKS-WAGNER. The NIH human genome project was specifically designed to fund research in a limited number of organisms. Organisms that fall without those, that kind that I mentioned, cannot be funded by human genome dollars. Those genome dollars also are meant for direct research, not for building large core facilities. They can be used like in, say, product design and robotics for something small, but not in building the structure or the infrastructure we need.

In regard to how do you set those up, it turns out that at the University of Oregon, there are now four or five faculty that have major projects using genomics. These are all faculty that are tenured and previously had been there. We now have just sent out an advertisement for a new genomics person working on mouse genetics, we hope. We don't need new positions from the State in order to require this facility. We can tap into these sorts of resource funds from the Federal Government for our research grants if we have such facility.

Also, one last comment, is that we've contacted several private foundations and we're actually negotiating with one private foundation right now for a substantial contribution toward building such a core facility. However, we need matching funds. We need other support to come in and help out with that.

Chairman WYDEN. Let me see if I get it, then, in terms of the foundation because you all have made a very good case. You'd like to see the State of Oregon put a higher priority behind human genome research, and that this would have at the center a commitment from higher education and help for developing a core facility.

When you got a core facility, that would be the kind of, to use your words, the jump start and then we would be in a position to get additional dollars from the Federal human genome project and free up good souls like Dr. Hoatlin to do this basic research rather than spend your time writing grants.

Is that a fair rendition of what's ahead?

Mr. MEEKS-WAGNER. I think that's fairly accurate. I think that you can take it one step further. After the universities become charged this way, then I think biotechnology firms would be very

interested in coming in and setting up collaborations in the systems.

Chairman WYDEN. Let me recognize my colleague, if she'd like to say anything in conclusion.

Ms. FURSE. I guess the only thing I would say is I am very interested in following up at some later date about this ethics issue. Because I do think you have put your finger on something that is—the general public is concerned about.

But other than that, thank you, Mr. Chairman. I really appreciate the opportunity to have been here. It was an excellent hearing.

Chairman WYDEN. Well, let us definitely follow up on the ethics issue. In a sense, the ethics debate was really launched by the Oregon health plan, because the Oregon health plan began to get people to swallow hard and make some judgments about what our priorities ought to be.

Now, we've got to take that debate much further along in the public policy arena as it relates to issues involving gene therapy and the human genome project.

Let me just leave you by saying I think y'all are doing some of the most important work possible in our State. I think when we look to the future, it's going to be in these information, knowledge-driven areas of science and technology. Congresswoman Furse and I are going to be anxious to spend a lot of time with you and to follow up on suggestions.

So we thank all of you. Do any of you have anything you'd like to add in conclusion?

All right. The subcommittee is adjourned.

[Whereupon, at 11:59 a.m., the subcommittee was adjourned, subject to the call of the Chair.]

APPENDIX

Statement of Representative Elizabeth Furse
Hearing of the Small Business Committee
"The Future of Biotechnology"
October 17, 1994

It's such a pleasure to be with all of you today. I want to thank my friend from across the river, Rep. Wyden, for taking the time to have this important hearing of the Small Business Committee. New ideas are nothing new to Oregonians, and there is truly an entrepreneurial spirit in the small business community of our state. With so many promising industries, it is no wonder Oregon has a well-deserved national reputation for being on the cutting edge. Biotechnology is one of those cutting edge industries, one which holds a tremendous amount of promise for everyone in the Pacific Northwest.

For too long, however, government and industry have been working against each other. Fledging industries which became solid cogs in our economic machine were built on the brains and brawn of small business entrepreneurs alone, often despite interferences from government. As we move more and more toward a global economy, industrial policy in America is changing. For the first time in our history, government and business are trying to work together as a team to try and keep our country's competitive edge. That's what this hearing is all about today: how can government help biotechnology, and how can it get out of the way.

The three panels appearing before the Committee this morning -- one on Access to Capital, one on Environmental Biotechnology, and one on the Human Genome Project -- should provide an excellent overview of the relationships between industry, science, academia, and government in biotechnology in America today. The future of biotechnology is of heightened importance for Oregon because it has been targeted as one of the key future industries in our region's economy.

I'm pleased that we have a panel testifying today on environmental biotechnology. As many people know, this year I had the opportunity to co-author and pass in Congress the Environmental Export Promotion Act. This new Act will help all Oregon businesses which produce environmental technologies, goods, and services -- often referred to as "envirotech" companies -- find foreign markets in a truly booming sector of the global economy. Currently, the world market for environmental technologies is about $200 billion. It is expected to triple to $600 billion by the year 2000. Oregon companies, due to our country's environmental standards, have a leading edge in the export of these products and services. In addition, envirotech jobs are good, family-wage jobs. In Oregon, on average, they pay $9,000 more than the next closest industry. I believe they are the family-wage jobs of the future. The Environmental Export Promotion Act will create thousands of these jobs in Oregon by tapping foreign markets. I like to say the Envirotech bill helps Oregon clean up in the job market by cleaning up the globe. Environmental biotechnology is a big part of biotech's future in our region.

Exports are only part of the equation, however. Research and development is key to biotechnology's future. The relationships between science and business are important ones which I hope we explore today. Technology transfer is also an exciting part of making biotechnology a long-term player in our economy. Most importantly, however, I hope people tell us -- the people who represent you in government -- exactly what we can do to help, and exactly what we can do to get out of the way.

Thank you all for coming. I look forward to hearing your testimony.

Statement of Ron Wyden, Chairman
Subcommittee on Regulation, Business Opportunities and Technology
House Small Business Committee

Field Hearing on the Biotechnology Industry
and Its Impact on Small Business
October 17, 1994

Today the Subcommittee on Regulation, Business Opportunities, and Technology will examine how the federal government can be a better partner to Oregon's promising biotechnology industry.

The Oregon Biotechnology Association defines biotechnology as "the industrial use of living organisms to enhance life." The field is a potential Oregon economic bonanza, creating family wage jobs through the development of products that can heal disease, feed the hungry, and clean up the environment. State officials recently named biotech one of its 13 "key industries" in its long-range plan for economic development.

The reality is, Oregon's biotechnology industry is still in the cradle. The federal government needs to take action to foster its growth. The challenges are staggering. This knowledge-driven industry is built on research and discovery -- Oregon entrepreneurs may have to sweat and toil for years before their products are ready for market.

In Oregon, experts believe that 5 fields are particularly promising. They are neuroscience, which explores the nervous system and the brain. Environmental biotechnology, that seeks to attack pollution and hazardous waste. Agriculture and forestry applications, often involve cross-disciplinary research, and can be key to generating sustainable food and wood production. Clinical services target diagnostics and therapeutics for the health care industry, and bioelectronics using biomolecules in the development of new information technologies.

The problem of access to capital is paramount. According to the Ernst & Young Ninth Annual Report on the Biotech Industry, financing is the most critical challenge for a biotech company. Many more companies fail for lack of financing than because of problems with their technology.

The average cost of developing a single human therapeutic product is $359 million. The product approval process lasts about 12 years. Stock prices can be weak, the initial public offering market can be soft, interest rates high and venture capital scarce.

The industry is getting better at raising money, but research and development requirements continue to rise. The median survival index, which measures a firm's cash on hand divided by the rate at which it spends, is just 25 months, down from 34 months a year ago. The percentage of companies with survival indexes of less than one year jumped from 17% to 26%. Only 22% of firms have enough cash to

last five years, compared to 30% in that position a year ago.

With money tight, some companies are forced to rush early-stage research (which risks derailing the product approval process later) or even toss overboard promising projects.

Congresswoman Furse and I understand the urgency behind the call for expanding access to capital for Oregon's biotech companies, and we look forward to exploring this issue this morning.

In addition, the industry has asked the Subcommittee to look into the availability of federal research funds for Oregon institutions. Oregon biotech companies are seeking more opportunities to work with university researchers, and the possibilities here are substantial.

For example, the federal government has agreed to spend $3 billion over 15 years on the massive effort to map the gene sequences in human DNA known as the Human Genome Project.

We would like more of the Human Genome Project dollars allocated to Oregon research facilities. This would help attract more scientists to the state, stimulate more sharing of research and technology transfer, and give Oregon private sector entrepreneurs a chance to tap the advances made through taxpayer-funded research.

Congresswoman Furse and I have worked closely with the biotech industry. Congresswoman Furse authored the Environmental Export Promotion Act that will dramatically expand opportunities for Oregon companies to export environmental technologies. The Congresswoman has been a leader in the effort to protect stock options, a key financial tool for small companies trying to attract talented workers.

As Chair of this Small Business Subcommittee, I have also taken a special interest in biotechnology. For example, after Subcommittee hearings exposed crippling delays in the review of biotechnology patent applications, the U.S. Patent Office tripled the number of patent reviewers and substantially reduced delays in the biotech patent review process.

To help address the industry's chronic shortage of capital, I recently introduced the "Entrepreneurship Promotion Act," which will provide a capital gain tax roll-over, similar to the one used by homeowners, for investors who sell their stake in one small business and reinvest a portion of the proceeds in another small business.

And now, I yield to my colleague Rep. Furse for her opening statement. She has made real, tangible contributions to assisting our biotechnology industry, and it is a pleasure to team up with her today.

Congressional Subcommittee Hearings on Small Business
Portland, Oregon -- October 17, 1994
Presiding -- Congressman Ron Wyden
Congresswoman Elizabeth Furse

Testimony of Dennis Borden, PHD, Asst. VP-Research
Administration, Oregon Health Sciences University

In this testimony I would like to touch briefly on three subjects that affect current research in genetic science. The first of these is funding; the second the issue of bioethics; and lastly the relationship of genetics and universities with commercial biotechnology enterprises.

Oregon Health Sciences University (OHSU) has many investigators and projects involved with the elucidation of human genetic mechanisms. For the fiscal year ending June 30, 1994 OHSU received more than $73.5 million in externally funded projects; approximately 85% of this funding was provided by the Federal Government. A significant portion of the funding is in support of education and training, as well as public health and rural health initiatives. However, the largest proportion of the funding (approximately $54 million is for basic and applied research and almost all of these funds derive from the National Institutes of Health. Genetic research can be broadly defined to include all of biological research, but more pointedly we can define genetic research as the examination of genetic material (DNA and RNA) and the interaction of these materials with the environment (including the microenvironment of proteins and molecules) and the macroenvironment of people, other organisms and "things". Using this more restrictive definition about 60-65% of the research at OHSU is "genetic" research, and this is supported by about $34 million.

OHSU has the missions of education, patient care, research, and public service. These are exemplified by the commitment of the Institution's President, Dr. Peter Kohler, and the dedication of the faculty and staff in fulfilling the aspirations of the citizens of Oregon. Virtually every activity of the University involves multiple components of its mission, and all of the interactions create the synergy of a contemporary academic medical center.

In order to gauge the "power" of genetic research, it is worthwhile to examine some of the projects that have recently been completed or are currently underway. I will rely on that important journal of scientific reporting known as "The Oregonian" and I use this to help us recognize the degree to which are citizens are being bombarded. OHSU investigators have recently identified the genes for colon cancer and episodic ataxia. A major grant was received this past summer for the study of and identification of the gene(s) involved in Fanconi

Anemia. Recently, a major award was made for studying the interaction of stress on the human genome. It has just been announced that one of OHSU's research centers, the Center for Research on Occupational and Environmental Toxicology -- CROET -- has been awarded in conjunction with the Portland Veterans Administration Medical Center, one of only three national grants to study the effects and hopefully, the resolution of problems of Gulf War Syndrome. Other studies include the effects of cocaine, other opiods, and alcohol on the pleasure centers of the brain. Recently, Dr. Susan Amara of OHSU's Vollum Research Institute was named a Howard Hughes Medical Institute Fellow for her contributions in the field of cocaine addiction and Dr. John Crabbe (a joint investigator of the University and the VA) along with his collaborators have received major awards for the study of genetic adaptations associated with alcohol usage.

As recently as the Friday past Oregonian (October 14), it was announced that a group of investigators (not in Oregon) have discovered a probable link between dyslexia and the genome. Several weeks ago, Nature magazine reported a probable link between the genome and insulin dependent diabetes. These complex multi-genic disorders are among the very first other than comparatively simple traits to become amenable to genetic analysis. It seems as if perhaps hundreds of human disorders have become amenable to genetic analysis. We have quite away to go as more than 10,000 genetic diseases have already been recognized and cataloged.

The issue of collaboration is vital to the progress that can be hoped for in this important field of inquiry. OHSU investigators maintain daily contacts with VA counterparts, but also have an extensive network of colleagues throughout the Oregon educational system and indeed, the world at large. The opportunity to share special equipment and expertise is a major driving force in establishing these relationships.

The crucial issues in having the highest quality of research enterprise, and thereby results with the greatest impact, are **FUNDING** and **INTELLIGENT, MOTIVATED INVESTIGATORS**. As might be expected, these two are not independent, but are inextricably linked. I have been associated with nationally funded research programs for about 30 years, and I truly believe that we are facing a national crisis at this time. I would not question the self-serving charge leveled against scientists who continually "cry poor"; of course scientists are protecting their interests. The issue for Congress is (as always) to what extent, if any, is the national future being compromised. I contend that current funding policy may severely damage our country if a longer term perspective is utilized. My experience is with the NIH, so I will use that as an example with little information about the broader domain of all other federal sponsors of research. Therefore, my numbers may not always be accurate, but I believe

the conclusions are. Current funding levels at the NIH for individual-investigator-initiated research is at about the 10% level. This is a considerable drop from "the golden days" of the 60's and 70's, when funding levels were in the 25-30th percentile ranges. The effects are to limit the number of scientists who are successful; to frequently exclude both younger, less experienced investigators as well as creating hardships for those near the end of their careers; and to cause many young people who might otherwise consider a career in science to opt for an occupation with a more secure future. In the not very distant future, this could have a devastating effect on the technological edge and competititive advantage of the United States. Fewer people are entering sciences; the primary schools are reporting lower scores in science and math; science is popularly portrayed as the plaything of rich and indolent individuals. If we were to lose but a single generation of the highest levels of technological development, we would soon find ourselves allied with third world countries and at the whim of our competitors. Can we afford the risk? It is my sincere hope that Congress will not allow that to happen.

In addition to the overall funding needs, it is essential that many of the operational characters of funding be changed to accommodate increased productivity. These include reduction of bureaucratic mechanisms which present unnecessary barriers, shorter cycles, more diverse programs for funding entering investigators, and perhaps many more. Both Dr. Varmus of the NIH and Dr. Lane of the NSF have committed their agencies to improvements and we hope that Congress will support their efforts.

The issue of how genetic science should be used, especially in the areas of gene therapy and the development of transgenic organisms is of paramount importance in our society today. Recently a French scientist proclaimed upon his retirement that the world should institute a 50 year moratorium on such practices. Not only is this unrealistic, but this ignores and demeans the countless victims who suffer from genetic disorders. The thought, however, is correct, that we are not well prepared to deal with all of the ramifications of our new knowledge and it is in the public interest to support an extensive debate on these issues. Whatever little is currently being done, is woefully inadequate given the power that the new technologies encompass.

Lastly, I would like to inform the Congressman Wyden and Congresswoman Furse about OHSU's relationships with commercial ventures, in particular with reference to emerging biotechnologies. More than 75% of OHSU's relationships with industry involve performance of clinical trials on a fee for service basis. Of the remainder, the vast majority of arrangements are straight forward licensing for a particular

technology invented by an OHSU investigator; about 80% of these activities are done on a non-exclusive basis, with the technology being made broadly available to many prospective licensees. In a very few cases, three to be exact in the last three years, several OHSU technologies have been licensed to new start-up ventures. In large part, this reflects the aspirations of the inventor(s) and the University's belief that a start-up company represents a realistic mode for the technology's development. Except for a tiny amount of cash, the only benefit to accrue to the University so far has been the promise of future interests. We hope these ventures gain success and that OHSU will be among the beneficiaries of those successes. It is important for Congress to understand how our University (and to extrapolate to our sister institutions) will utilize these benefits. It is OHSU's hope to be able to fund graduate education programs, pilot type studies that have difficulty receiving sponsorship, bridge funding for projects that have experienced lapsed funding, and prototype development for new technologies. These goals are dictated not by any sense of altruism, but by facing up to the demands of our mission. In general it is my belief that the ways in which universitas will profit from their interactions with commercial ventures will be to enhance the processes to which they are already committed.

Testimony for the Small Business Subcommittee
on
Business Opportunities and Technology

Portland, Oregon -- October 17, 1994

Testimony provided by Art Hiemstra, Regional Vice President, Silicon Valley Bank

The creation on a new company, a new biotechnology company, takes place when there is a confluence of several ingredients: management, scientific discoveries, market opportunity and capital.

A company missing any of these ingredients will fail, and even with good science and management a company will not be able to attract capital without a good market opportunity. Of these ingredients the one I would like to address is capital.

From the time a biotechnology company is formed to the time it becomes commercially viable typically takes five to 10 years. While the company is developing its technology, conducting trials, and undergoing regulatory scrutiny it spends substantial amounts of cash for salaries, for equipment, and for the many activities that support the research and development effort. We have seen this process consume tens of millions of dollars.

Private and public investors have provided the bulk of the capital for the industry -- for the good things the company can accomplish and for possibility for substantial return on investment.

As the industry has grown a number of sources of capital have become available, and I represent a commercial bank that has devoted great effort to understanding the underlying business risks of the biotechnology industry.

We have concluded that despite the long development cycle, and the losses incurred by biotech companies in their early years, loans can be made available -- but only as a portion of an overall capital structure that is predominantly equity financing.

Our involvement has leveraged the dollars raised through the sale of stock and allowed the biotech companies to focus the more expensive money raised from investors on basic research and development, while financing the acquisition of depreciable assets with lower cost debt capital.

This complementary financing strategy has helped biotechnology companies stretch the equity investment and put more dollars into research.

As a lender, we take great comfort when a biotechnology company finances its operations with capital provided by sophisticated private or corporate investors because their

involvement is a stamp of approval on management, on the science and on the market opportunity.

Implicit in their decision to invest is an underlying expectation of the need to continue to provide financial support to the company during the years and years of development --of course presuming the company continues to make progress in product development.

When debt capital is layered on top of equity investment the biotech company has more resources and can accomplish more between financings. As a result the equity investors gain greater value for their investment, and we are more likely to be repaid, because the company is making progress and attracting continued investor interest.

Our lending activity to the early stage biotech companies is predicated on this continued support from investors. Since we are making loans to companies who are losing money, and will continue to do so for several years as they make discoveries that lead to products, we need to assure ourselves that investor support will be forthcoming in future years.

As a result we are greatly concerned with and monitor the flow of capital to professional investors and subsequently to industry segments such as biotechnology. We think congressional actions such as the Entrepreneurship Promotion Act of 1994 introduced by Congressman Wyden will be helpful because they encourage the flow of capital to professional investors.

And perhaps tax deferrals such as this will make it easier for another type of company to attract investment. The majority of new companies will not be able to attract professional investment -- most typically because the development of their science is too speculative or it it too hard to prove the market opportunity will allow the creation of a large enough company to provide an attractive rate of return in investment.

These companies often only need a few hundred thousand dollars to prove their concept and develop information on the market. For them, private equity, typically from seed capital investors is needed. There is a scarcity of this form of capital and the scarcity has hampered the development of biotechnology in Oregon.

We encourage your continued attention on the industry and on the kinds of legislative actions that will encourage the flow of capital to both the large investor and the small investor who, in particular, can make a large impact on new companies when they are at an embryonic stage and need smaller amounts of money.

My name is Maureen Hoatlin. I am an Assistant Professor at Oregon Health Sciences University (OHSU) in the Division of Hematology and Medical Oncology. I am interested in understanding the molecular mechanisms of hematopoietic diseases (those diseases that affect cells in the blood) and to develop gene therapy at OHSU. Gene therapy is a new technique that shows great promise for the treatment of genetic diseases, as well as other diseases such as cardiovascular disease, cancer and AIDS. A very general definition of gene therapy is "the transfer of new genetic material to the cells of an individual with resulting therapeutic effects." There are two excellent reviews on this subject listed in the bibliography. My particular focus at this time is Fanconi Anemia, a very rare fatal children's disease. A large NIH grant has recently been awarded to OHSU to support the work of the many scientist and physician teams that are working together to understand and cure Fanconi Anemia.

I am presently trying to establish a laboratory that will be a source for OHSU researchers for gene therapy vectors (viruses engineered to enable the transfer of the new genetic material), not only for Fanconi Anemia, but for use in treatment of other diseases as well. This laboratory is just one example of a laboratory that can be viewed as a hybrid between an academic research laboratory and a private biotechnology research and development lab. I have had professional experience in academics as well as private industry, and I feel strongly that separation of academics and industry is no longer adequate for the revolution in biomedicine that we are now beginning to experience. We need to combine the strengths of both if we are to take advantage of the technology at hand. For example, in

the case of gene therapy applications, the disease gene must be discovered, the normal gene must be isolated and placed into a suitable vector for gene transfer, and then the vector bearing the correct gene must be produced according to strict guidelines for safety and efficacy. The vector is then administered to the patient in a clinical setting. The corrected cells from the patient must be followed over time to ensure that the transferred gene is still functioning. Clearly, an academic lab would have difficulty funding the expensive production facility required to make and test the vectors. At the same time, research in gene discovery, the basic research involved in transplant biology, and the post-treatment patient follow-up would be difficult to do in industry. There are additional reason that a academic-private hybrid laboratory would be ideal. First, gene therapy vectors for the treatment of diseases of low incidence, such as Fanconi Anemia, could be developed by academic researchers and produced by the private lab in small batches. In this way, it would be economically feasible to treat diseases affecting a small number of patients. Second, the constant hunt for funding that most academic scientists now endure (see ref 3) might be partially alleviated by the availability of these expanded resources. The talents of trained and dedicated scientists would undoubtedly be more useful in the laboratory than in the relentless and often unsuccessful hustle for grant money.

There have been agreements between research and industry called CRADAs (Cooperative Research and Development Agreements). CRADAs were established by the Federal Technology Transfer Act of 1986 (see NIH publication No. 93-2888). In this agreement the

private company serves as an adjunct laboratory to the University laboratory and the pooled resources of both labs help achieve research goals. This would be one possible mechanism for encouraging biotechnology growth in Oregon. Other Universities are funding these particular vector production facilities in various ways. For example, some states refund indirect costs to the university, the associated hospitals award money to fund genetic research/gene therapy development, and the state gives a large award to the university for development of gene therapy resources over a five year period.

This is the best possible time to be doing biomedical research. The technology for disease gene discovery and correction is in place or developing very rapidly. The payoff for all of the past years of research funding is here. I believe that the cost of treating patients using gene therapy will be offset by the gain in quality of life and reduced health care costs for these patients over the long run. I cannot overemphasize how much I think Oregon would benefit from an increased commitment to genetic research. Discovery of new disease genes, methods of treatment and diagnosis would likely develop biotechnology industry in Oregon, as well as attract grant money to expand basic research in the academic setting.

References

1. Curing Disease through Human Gene Therapy. NIH publication No. 93-2888. July 1993 (An excellent lay review, mentions CRADA). Attached.

2. Morgan, R. A., and F. Anderson. 1993. Human Gene Therapy. Annu. Rev. Biochem. 1993. 62: 191-217.

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OLYMPIC VENTURE PARTNERS

TESTIMONY

For The Congressional Record

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Fostering Biotechnology In Oregon

While capital availability is an issue worth addressing on the tax policy side, larger gains can be made by providing biotech companies (and their investors) a shorter and more certain path to regulatory approval.

PORTLAND, OR, Oct. 17, 1994 -- Olympic Venture Partners is pleased to be asked to comment on the issue of access to capital for the biotech community, and what the Federal government can do to improve the situation.

1. Biotech companies have large appetites for capital. The typical new drug discovery company will spend well over $100 million dollars to get its technology through R&D, into product development, through clinical trials and regulatory approval.

2. Sources of capital for biotech startups include: government research grants, (which are extremely important), private investors (aka "Angels"), professional venture capitalists, foreign and domestic corporate partners, and public investors. The acquisitive nature of offshore entities does raise some issues regarding national interest in our intellectual property. A new model in the capital field includes "Huge Angels" (Bill Gates, Paul Allen, etc.) partnered with non-traditional, industry-targeted merchant bankers.

-more-

3. The largest barriers in the private sector which limit the capital flow to biotech are fear of regulatory change or delay, lack of preferential treatment of capital gains to offset the risk and illiquidity taken on by early investors, and lack of expertise by private investors in the complexities of starting, growing and financing biotech companies.

The largest barrier raised by the Federal government is the uncertain timing and outcome young companies face in dealing with the FDA, EPA and other regulatory bodies. Early investors must factor in the time value of money in their return calculations. If the marked increase in company market value which comes with the ability to actually sell product in the US is pushed out by a number of years, not by actual concerns over the safety or efficacy of the product but by the process itself, biotech investments become far less attractive. That is, in fact, the picture which we see today.

4. H.R. 5201 appears to be a useful bill to increase the attractiveness of providing early risk capital to small companies by individual investors and in attracting individual managers to these companies. It will not have any impact on increasing the funding levels for professional venture capital partnerships, since the tax free rollover provisions of the bill will not be useful in these closed-end limited partnerships. Since venture capital firms serve a major role in this industry, providing expertise in not only evaluating and funding biotech opportunities, but helping them with guidance as they grow, the bill will not produce the degree of improvement which might be expected. However, it is a step in the right direction.

Olympic Venture Partners is the leading technology-focused venture capital firm in the Pacific Northwest, and the only firm with offices in both Oregon and Washington. Funds under management total over $100 million, sourced from institutional investors. Partners George H. Clute, W. Denman Van Ness, and Charles P. Waite, Jr. work out of the Kirkland, WA office, while Gerard H. Langeler works out of the Lake Oswego, OR, office.

UNIVERSITY OF OREGON

October 12, 1994

The Honorable Ron Wyden
United States House of Representatives
Committee on Small Business
B-303 Rayburn House Office Building
Washington, DC 20515-6318

Dear Congressman Wyden:

I am privileged to offer the following as testimony in enthusiastic support of government assistance for establishing and promoting both academic and private biotechnology research in the area of "genome science." I look forward to participating in the hearing on this matter to be held on October 17, 1994.

I sincerely hope that your Committee will consider the benefits of supporting the development of genome research in the State of Oregon, and be able to act accordingly.

Respectfully,

D. Ry Meeks-Wagner
Associate Professor of Biology
Member, Institute of Molecular Biology

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Summary of testimony from Dr. D. Ry Meeks-Wagner.

I am privileged to offer the following as testimony in enthusiastic support of government assistance for establishing and promoting both academic and private biotechnology research in the area of "genome science." In my testimony I will refer to genome science, including the Human Genome Project, as "genomics." The field of genomics is just beginning to make major contributions to improving our world in a wide variety of areas, including medicine, psychology, sociology, agriculture, forestry, and fisheries. My own research is conducted at the University of Oregon. I am engaged in two major areas of research, both of which are involve significant use of genomic approaches to biology. It is obvious to me that the future will indeed be very exciting!

I strongly support the development of genomics in the State of Oregon. Oregon is in a unique position to both contribute and benefit from genome research. We have the academic environments required to foster creative investigations in genomics. For example, the University of Oregon is ranked in the top 10 in the United States in the biological sciences (including both public and private institutions) based on the "scientific impact" of research published in peer reviewed journals; Oregon Health Sciences University is ranked as one of the top medical schools in the United States; Oregon State University has some of the top programs in the United States in agriculture, forestry and fisheries. Furthermore, Oregon is making excellent strides in developing first-rate private biotechnology companies.

Given the strength of the academic institutions, and the benefits of residing in Oregon, I expect that biotechnology firms will find Oregon a good place for business. Genomics is field that will spark the innovation of an amazing number of different biotechnologies, but what is needed is a mechanism to first "jump-start" genome research initiatives in Oregon's Universities. By building upon the already excellent programs that exist at the University of Oregon, Oregon Health Sciences University and Oregon State University, collaborations with private businesses will be fostered, and this, in turn, should lead to the development of new biotechnology firms within the Eugene-Corvallis-Portland area. This is exactly how public-private sector biotechnology collaborations have evolved in other academic centers such as the Tacoma-Seattle-Everett area, the San Diego area, and the Boulder-Denver area.

In order to continue existing lines of research, and to develop new research directions, I believe it is essential that several "genome research centers" be created right here in Oregon. I imagine that these would operate as "core" facilities that would serve as the basis for genomics research, and would provide many aspects of genome analysis (including the robotics needed to efficiently carry out genome research) for researchers in the state and in other Northwestern states. One aspect of

such new centers is that funds should be earmarked for aiding the development of new genome research projects in addition to the Human Genome Project.

When the Human Genome Project was initiated several organisms were designated as models for developing the technology and biological basis for human genomics. This group of a few organisms (yeast, *C. elegans*, fruitflies, mouse and humans) is now obsolete in terms of the potential impact that genomics can have on human health. For example, genomic analysis in other organisms is suffering due to exclusion from this list, and yet there are clear implications for benefits from such research to humans. Plant genomics can lead to more direct and better strategies for crop improvement; cattle genomics can lead to improved breeding for milk and meat production, as well as disease resistance; zebrafish and dog genomics can lead to an understanding of human development and behavior impossible to obtain by limiting genomic research to mouse and humans. I believe that the exclusion of these organisms from the current genome budget is simply a reflection that no one really could have guessed the tremendous impact genomics would have on health and agricultural related sciences. Now is the time to correct this situation, and Oregon is in a unique position to take the lead in doing so.

The creation of several "Centers for Genome Research" would, of course, need to be done in conjunction with adding new faculty positions to the host institutions. Once this is done, there would then exist the ability to attract private biotechnology interests that would be eager to take advantage of using the core facilities, and take advantage of establishing collaborations that potentially could lead to human therapy and agricultural improvement products.

I believe that it is essential for Oregon universities to become active players in the field of genomics: the Universities are, without question, the ground level, the seeds of inspiration, for future progress in this area. Establishing Centers for Genome Research would benefit both citizens of the United States and citizens of Oregon. There are many reasons for establishing Centers for Genome Analysis in the State of Oregon. As described above, Oregon has the outstanding academic environments required to foster creative investigations in genomics. Furthermore, Oregon is actively developing a successful private biotechnology industry.

In addition to creating a new employment base in biotechnology, the citizens of Oregon would benefit by having close at hand the resources to address many local (state and regional) issues that genomics impacts. These issues range from new methods of diagnostics and therapy for human illness and abnormalities, to discovering information related to agricultural, forestry and fisheries improvement and conservation. At present such issues can not be addressed efficiently by research or services within the State of Oregon. We are fast becoming a

State dependent upon our neighbors to provide what should be basic services and product designs capabilities. The time to change this is now: in a few years we will be so far behind that we will not be able to participate in what is perhaps the greatest improvement in the human condition in modern times.

Statement on my research programs, and on other genetic research programs at the University of Oregon:

My own research is in two major areas. The first area of is an analysis of the genetic control of flowering in higher plants. Here we have identified (by mutation) several key genes that appear to "connect" the internal biological "clock" to the process of flower formation. Currently scientists understand very little about the biological clock, but we do know that this internal pacemaker establishes many aspects of an organisms growth, development and behavior. At present the best "model" systems for reaching a true understanding of the "clock" are fungi, fruitflies and plants, because all of these organisms have clock-related processes that are easily identified and studied. However, given the amazing degree of conservation of biological mechanisms, it is expected that the analysis of the biological clock in these organisms will be directly applicable to the clock in humans, and should lead to an understanding and treatments for many human physiological disorders related to the function of the human clock. This research is currently funded by the United States Department of Agriculture Competitive Research Grants Program, and the American Cancer Society.

The second area of research is a relatively new line of investigation that I have entered in collaboration with other researchers at the University of California, Berkeley, the Fred Hutchinson Cancer Research Institute in Seattle, and here at the University of Oregon. This project is aimed at using the domestic dog as a model for understanding the genetic control of animal development and behavior. The emergence of genomics as a field of biology has now opened up previously impossible research situations. Genomics is based on the original principles of genetics developed by Mendel one hundred years ago: 1) heritable differences can be understood in terms of fairly simple patterns, and 2) if differences exist between related individuals, then those differences (i.e. genes) can be mapped and isolated. The domestic dog provides an excellent source of "differences" in size, shape and behavior. In theory, the genes responsible for these traits can be identified and isolated using genome analysis.

My particular interest in the "Dog Genome Project" is the identification and analysis of the genetic basis of complex behaviors such as attention span, avoidance and aggression. Many domestic dog breeds that display very large differences in these

these behaviors have been created in just the last 100 to 200 years. This rapid breeding for "desired" behaviors strongly suggests that only one or several genes control many of these characters. Genomics should allow these genes to be isolated, and molecular biology should permit the analysis of how these genes control the expression of the various behaviors. Again, given the large degree of genetic conservation between mammals, many of the genes that control these behaviors are likely to also influence human behaviors. Thus our understanding of these traits should directly lead to the development of treatments or therapy for related human conditions. Significant advantages of performing the initial studies in the domestic dog are: 1) the genomics approach is almost entirely non-invasive (i.e. no animals are sacrificed or subjected to surgery in this study); 2) all animals in the study are kept as private pets, thus greatly reducing the cost of the project; and 3) directed breeding is performed between dogs in the study in order to complete detailed genetic analyses of the traits being examined. This work is funded by an NIH grant to myself, and by funds awarded to the collaborating investigators.

Other genetic research being carried out at the University of Oregon is also at the cutting edge of the field. For example, over the past 10 years the zebrafish has become a model organism for understanding the development of the vertebrate body plan and nervous system primarily due to the work of scientists at the University of Oregon. This year, colleagues at the University of Oregon published the first map of the zebrafish genome. Already the use of genomics in conjunction with this map has led to identification and isolation of 3 genes essential for normal body development. In addition, it has been shown that all of these genes exist in mammalian genomes, and it is currently hypothesized that they play a critical role in regulating aspects of human development. Other laboratories are making use of genetic and genomic research with the model animal system, *C. elegans*, and with common baker's yeast, in order to determine how cells communicate with one another to specify normal growth and development. Yeast and *C. elegans* are serving essential roles in as models for the human genome project.

Funding for this type of research is a significant issue, and my comments are base on personal experience in obtaining funds, as well as experience as a panel member for NIH and USDA competitive grants programs. In the past decade federal support from NIH, NSF, USDA, and DOE has not been able to keep up with rate of growth of excellent research in the basic sciences. It has been increasingly difficult for individual investigators to find adequate support from these agencies to develop their research programs. It is essential that individual scientists be supported to follow their own creative routes in order to maximize the chances of human benefits from basic research. In these days of declining support only the upper 3% to 20% (depending upon the agency and program) of research grants are funded, and rarely is funding at a level necessary to complete the work as proposed.

This trend has led to a situation where the "big get bigger" and the "small disappear". Thus, in order to survive in basic research in an academic environment it essential to have established good collaborations with other groups, so that their expertise can be freely shared. At present, my "biological clock" research involves collaborations with scientists at the University of Virginia and Ohio State University. In order to move this project to the next level, and to be able to clone and study the gene that controls the biological clock, I have been working to establish a collaboration with an investigator at Harvard University who has been one of the major contributors to genomics in plants. He recently agreed to become involved in this project, but given the distance from Eugene, and his busy schedule, I will not learn what help his research group can offer for another 10 days to two weeks. Having experienced first hand the difficulties involved in east coast-west coast and international collaborations, I am much more optimistic that the Dog Genome Project will rapidly become successful because all of the collaborators are located in Berkeley, California, Eugene, Oregon, and Seattle, Washington: in the same time zone, and only an hour or two flying time from each other, with Eugene often serving as a "middle" point for meetings.

As I stated earlier, I believe that it is essential for Oregon universities to become active players in the field of genomics: the Universities are, without question, the ground level, the seeds of inspiration, for future progress in this area. Establishing Centers for Genome Research would benefit both citizens of the United States and citizens of Oregon. In addition to creating a new employment base in biotechnology, the citizens of Oregon would benefit by having close at hand the resources to address many local (state and regional) issues that genomics impacts. However, we are fast becoming a State dependent upon our neighbors to provide what should be basic services and product designs capabilities we should possess. The time to change this situation is now, and the change can be made with a sound investment right here in Oregon.

Thank you for your consideration of my testimony.

Respectfully,

D Ry Meeks-Wagner

D. Ry Meeks-Wagner
Associate Professor of Biology
Member, Institute of Molecular Biology

TESTIMONY
US CONGRESS FIELD HEARINGS

BIOTECHNOLOGY IN OREGON

PORTLAND, OREGON
OCTOBER 17, 1994

NANETTE NEWELL, Ph.D.
EXECUTIVE DIRECTOR
OREGON BIOTECHNOLOGY ASSOCIATION
PORTLAND, OREGON
503-241-7802

Thank you for the opportunity to discuss an area of growing importance, the use of biotechnology to address environmental contamination. The commercialization of environmental biotechnology is an area that I have worked in for several years. I am the founder of EnSys Environmental, a publically traded environmental biotechnology company that uses modern medical diagnostic techniques to detect and quantitate toxic chemicals. The other areas I have explored include the use of microorganisms and plants to degrade toxic chemicals and composting as a way to limit the use of landfills.

Environmental biotechnology, defined as the use of organisms to perform a useful function, can include both the treatment of existing waste (bioremediation) and the treatment of waste prior to it leaving the factory (biotreatment). The organisms that degrade the waste can either be microorganisms or plants, and the waste can be either toxic or nontoxic. I am firmly convinced that only biotechnology can make major inroads into the cleanup of our current waste problems. It is a technology that is relatively inexpensive, can be used in situ, and does not require large energy inputs.

As with other areas of biotechnology, advances in environmental biotechnology will only come with technology generated from basic research. The early stages of this research were put in place in the late 1970's at the Department of Energy. Early in the Reagan Administration, however, all the funding for this research was canceled, and it has never been put back in place. As a consequence, industry is currently working with only a small fraction of the technological sophistication that is available. The current remediation methods only use organisms that are isolated from the environment. There is extremely little effort underway to use biotechnology's tools to improve those organisms so that they may compete efficiently with other technologies.

Because of the potential importance of biotechnological applications to the environment, it might be thought that industry would fund some of the basic research for organism

improvement. The reason it hasn't is because of the continuing uncertain regulatory environment at the EPA. For fifteen years, the EPA has been studying the results of the deliberate release of genetically engineered organisms into the environment. With hundreds of experiments now done and with absolutely no adverse consequences, the EPA still will not allow the widespread commercial use of genetically engineered organisms in the environment. The time has certainly come for the EPA to turn some of its risk assessment dollars to helping develop the positive uses of organisms in the environment. But until the EPA clarifies and liberalizes its regulatory policy, industry dollars will continue to be in short supply for developing more sophisticated organisms.

One other difficulty lies in the path of taking a new environmental technology to the market, and that is the incredible reluctance of the EPA and the large environmental consulting firms to adopt new technology. Unlike the FDA, there is no well documented testing procedure for new technology. Although there is no regulatory approval process for environmental products, they will not be used by the major environmental firms until they are "approved" by the EPA. This approval usually means being written up in one of EPA's method handbooks. Small companies often spend years and hire expensive consultants to get to the right people in EPA so that a new method can be "approved." This process not only puts up roadblocks for new technology, but also means that EPA approved methods are often archaic, time consuming, and costly.

I would like to propose some steps that Congress could take to remedy some of the above problems and to promote environmental biotechnology.

- o Fund basic science. Research dollars need to go to universities to improve our understanding of just how organisms degrade wastes. This is best done through a peer reviewed grant program best exemplified by NIH. Thus, I recommend your support of the proposed National Institute of the Environment, with the insistence that its research dollars be distributed in a peer reviewed manner.

  I also would suggest that some of the EPA funding currently spent on biotechnology risk assessment also be turned toward how we can develop efficient environmental organisms.

  Also, some of DOE's funding directed toward environmental cleanup could be spent on biotechnology applications.

- o Clarify the regulatory environment for genetically engineered organisms. If the EPA were to develop exclusions for certain classes of organisms known to be

environmentally benign as opposed to it's current case-by-case analysis, industry would likely show more interest in developing environmental biotechnology.

- Develop better ways for small companies to get their technologies tested and "approved" by EPA. The EPA needs to clarify how to get one's technologies into EPA methods books so that the major companies can be encouraged to use them.

Alan P. Timmins
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TESTIMONY TO THE
SMALL BUSINESS SUBCOMMITTEE ON
REGULATION, BUSINESS OPPORTUNITIES AND TECHNOLOGY

Portland Field Hearing
October 17, 1994

Good morning. My name is Alan Timmins and I am the Executive Vice President and Chief Financial Officer of ANTIVIRALS INC., an Oregon biotechnology company. I have been asked to testify this morning on the state of capital raising in the biotech field, and the impact that HR 5201, a proposal to amend the Internal Revenue Code to provide for nonrecognition of gain on the sale of eligible small business stock if the proceeds of the sale are reinvested in other eligible small business stock.

In discussing the capital needs of a biotechnology company it is first important to note that the definition of the term "biotechnology" has blurred. Initially, that term referred to the use of recombinant DNA technology to make human proteins (e.g. insulin, growth hormone, and erythropoetin). Today, the term no longer applies to only protein-based products, but to any company that is developing therapeutic products (i.e. drugs), developing diagnostic products, and even developing certain agricultural products.

Capital needs of a drug development company are truly staggering. The range of costs to bring a drug to market range from $100 million to $500 million, with the average somewhere in the $150 to $200 million range.

Diagnostic development companies face somewhat less significant cost hurdles. These companies' cost to market for a product are perhaps an order of magnitude less than those of drug development companies, with the actual figures dependent upon:

1) the complexity of the technology involved,
2) the degree of capital-intensiveness in the development cycle and production process, and
3) the level of FDA approvals required.

Capital needs, particularly in the drug development arena, are for four major purposes. They include:

1) a highly educated, highly trained, work force consisting mainly of PhD's in critical research posts, and often process engineers in later production development,
2) expensive instrumentation, which is often customized for the specific requisite applications,
3) facilities designed and maintained in accordance with the FDA's "good manufacturing practices" and "good laboratory practices", and
4) extensive, expensive and exhaustive testing in an attempt to receive FDA approval to market products in this country.

The typical sources of capital for the biotech industry have evolved dramatically in the last few years. Traditionally, much of the capital for biotechnology came from government grant programs designed to stimulate innovation. Additional capital was accessed through the venture capital community, and equity offerings in the public marketplace. Lesser volumes of capital were also garnered from corporate partnerships with larger pharmaceutical companies and through private equity offerings to institutions and wealthy individuals. A reshuffling of capital sources has now occurred. Now highly sought as a source of capital are the major corporate partnerships with major pharmaceutical companies. Also highly sought, but rare, are significant private placements with institutions and wealthy individuals. Venture capital investment and initial public equity offerings continue to be desired by some companies in the industry, but both these sources are ideally approached only after the achievement, or appearance of achievement, of significant scientific benchmarks. Government grant programs are now relatively rarely accessed, due both in part to the paucity of such programs and perceived cost/benefit relationship of the application process.

The biggest barriers in the private sector which limits the availability of capital to the biotech industry are time and cost to market. Aside from the substantial cost of bringing a product to market of $100 million to $500 million, the average time to bring the product to market is ten to twelve years. This substantial time commitment inherently increases the risk of loss of investment by decreasing the perceived liquidity. These factors increase the "hurdle rate" or expected rate of return that an investor must believe is forthcoming, or the investor will not provide capital. Because of these factors, the risk of loss of investor capital is extremely high and the time horizon for commitment of capital is long in comparison to investments in other industries. While the Drug Competition and Patent Term Restoration Act of 1984 allows for some extension of patent protection to compensate the patent holder for the time required for FDA regulatory review of the product, this extension in and of itself is not adequate to counteract the time to market issues and stimulate investment. Thus, the time and cost of the FDA approval cycle must be reduced.

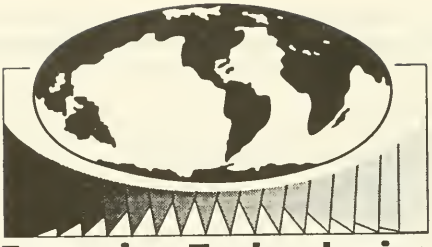
The proposed legislation, HR 5201, will definitely help small biotech companies raise capital. The legislation, however, only addresses the return portion of the risk/return decision that any investor considers, by enhancing the returns that an investor may accumulate. The legislation should be extended to further stimulate investment by reducing

the impact of losses on the investor either through tax credits for losses on small business investments, or through what I call "hyper-deductions," i.e. deductions of greater than 100% of losses on certain qualified small business investments.

Another necessary modification to the proposed legislation is to make a clear bridge between it and Internal Revenue Code section 1202(c), which limits the impact of capital gains tax on qualified small business investments held for more than five years, by the following means:

1) consistently define what constitutes a qualified small business to agree with IRC 1202(c), (i.e. IRC 1202(c) has a $50 million general threshold, where HR 5201 has a $20 million threshold), and
2) clarify the interaction between IRC 1202(c) and HR 5201 so that incentives to reinvest long term (i.e. held for more than five years) small business capital are maintained by not taxing gains reinvested at the higher capital gains rate, if such reinvestments are not held for greater than five years.

In summary, legislation like the proposed HR 5201 could serve as a valuable aid in capital raising for the biotech industry, but it must be modified to achieve consistencies and synergies with existing legislation. Further, no proposed legislation will have as positive an impact on investment in the biotech industry as significantly reducing the time and cost to market of products by streamlining the FDA approval cycle.



Emerging Technologies
INTERNATIONAL

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Statement for Congressional Record
Prepared
By William Weinstein

Biotechnology is the most cost effective remedy available to the environmental community for the cleanup of toxic organic contaminants that threaten human populations and ecological receptors. Unfortunately for the American taxpayer and for Americans in general, the use of biotechnology in the cleanup of hazardous materials is under utilized.

Biotechnology has been the province of small environmental cleanup companies such as Emerging Technologies. The use of bioremediation has been demonstrated to be highly successful in remedying petroleum hydrocarbons on various types of contaminated sites. The market for remediation of petroleum in the U.S. and abroad is never ending. However, there is a larger, more important market that includes cleanup of organic compounds that, to this date, are the most toxic contaminates released to the environment, pose greater threats to human and environmental receptors than do petroleum hydrocarbons, but are not being cleaned up by anyone because there are no effective cleanup strategies for most of these contaminates. They are being left in the ground at Hanford, Savannah River, and other sites, but the American taxpayer is paying Westinghouse and Bechtel Corp. and other large contractors to study them to death. We, in the business, call this excavation by sampling and when it costs hundreds of thousands of dollars to bore a 6-inch well at Hanford, we are puting our money into the wrong technologies.

The technology has not been extended to larger, more complex sites for a number of reasons, of which the most important are economic. Large environmental consulting firms control the environmental market. Until the implementation of the Superfund Accelerated Cleanup Model, the emphasis of the environmental business was on delineating the extent of contamination, but not on the cleanup of the contamination. On large Department of Defense and Department of Energy sites, biotechnology is subservient to the remedial investigation because for large contractors there is more money in investigation than in actual cleanup.

Biotechnology has not been extended to the most toxic organic contaminates such as chlorinated solvents because smaller cleanup companies have not had the capital to prove the effectiveness of bioremediation on such contaminates as polychlorinated biphenyls, trichoroethene, and dioxins. These contaminates can be remedied by biotechnology if the proper infrastructure is financed. Small businesses with innovative technologies need help to demonstrate the effectiveness of their products/technology and to be able to compete with larger contractors whose main interest lie not in cleaning up the contamination but rather in perpetuating the problem by continuing to investigate, delineate, and obfuscate.

I believe there needs to be regional centers to test technologies and facilitate the transfer of these technologies to mainstream environmental contractors. To demonstrate the effectiveness of biotechnology in remedying the most toxic organic compounds ETI along with the Oregon Department of Economic Development and the Oregon Environmental Technologies Association has proposed an Environmental Center of Excellence (ECE). The proposal of the ECE will be for the promotion of information and innovative technology transfer and export within the United States and to Pacific Rim Countries. The environmental information systems and innovative technologies (IS/IT) developed by the EPA superfund program represents a significant national investment. The effective export of regional and national IS/IT is dependent on building an effective marketing infrastructure involving Oregon large and small businesses, State Government, and Federal agencies. An environmental Center of Excellence will accomplish three interrelated goals: (1) transfer of IS/IT to Oregon State agencies and small businesses; (2) testing and development of innovative technologies to remedy point and nonpoint source pollution; and (3) marketing of IS/IT to Pacific Rim countries by small businesses.

Biotechnology and proper risk management techniques that are being pioneered by the Navy at Port Hueneme, Mare Island and Concord naval base in California should be carefully tested and packaged. It is my firm belief that with proper help, small business can lead the cleanup of our most toxic sites by year 2000. If the American people are still paying billions of dollars for investigations and ineffective cleanup processes in the millennium, then we have all failed in a significant and meaningful way.

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VECTORS™

Newsletter of the Oregon Biotechnology Association & Foundation

Fall 1993 Volume 3 Number 4

COMPANY PROFILE

EMERGING TECHNOLOGIES INTERNATIONAL

Emerging Technologies International, a biotechnology corporation, was founded with a commitment to provide quality environmental consulting and remediation services employing leading edge technologies and cost effective solutions. ETI consists of oil spill specialists, leading microbiologists, chemists, environmental physicists, marketing experts and governmental consultants. William Weinstein, city manager of Cordova during the Exxon Valdez oil spill, and Ken Garrett, equipment manager for Exxon during the same period, brought together this group of highly qualified and experienced biotechnology professionals to bring "closure" to specific environmental problems.

The environmental remediation industry is the leading new industry of the 90's. Bioremediation techniques offer significant benefits in terms of less costly, faster and lower impact solutions when compared to the conventional techniques of high temperature burning, vapor extraction and toxic dumps. No other solution favorably compares to the safety and effectiveness of bioremediation through the adaptation of Nature's own methods.

ETI offers leading edge technologies in the field of bioremediation. ETI's product lines include proprietary strains of hydrocarbon oxidizing bacteria. These bacteria, which form the basis for ETI's surfactants, enzymatic compounds and cold molecular cracking processes, solve a wide range of hydrocarbon contamination problems in soils and water.

The EPA is currently researching the degradation of soil contaminants using natural bacterial strains isolated, cultured and augmented into the soil matrix. The technical group of ETI has been involved in this research since 1968, and consequently, is on the leading edge of technology in the environmental industry.

ETI is currently working with Conoco, Chevron, the US Department of Defense, the US Navy and various consulting firms throughout the country. The technology is expeditious and effective for a wide range of contaminants, such as diesel fuel, creosote, and pentachlorophenol, resulting in substantial cost savings to their clients.

In addition to bioremediation projects, ETI has developed an excellent working relationship with the Russian Academy of Sciences and various Russian universities. As a result, ETI serves as a clearinghouse for the transfer of technologies in the fields of environmental science, medicine, microwave electronics, aerospace engineering and computer science, as well as a consulting firm that directs US technology into Russia. "Though ETI is involved in many projects outside its Portland home base," said Weinstein, "it is our wish to attract other businesses and people to Oregon to continue our own growth and to spark additional economic growth in the region."

For more information: William Weinstein; (503) 761-6247 or (503) 223-6880.

In This Issue

Emerging Technologies signs venture with Alaska company

By ANITA MARKS

A small Portland environmental firm is forming a joint venture with the native-owned corporation that provides spill prevention and clean-up services for the Alaska oil pipeline.

Emerging Technologies International, a local biotechnology firm that uses tiny bacteria to consume spilled petroleum products, has struck a deal with Chugach Development Corp. of Anchorage. Emerging Technologies' client list includes Oregon Arena Corp., Southern Pacific Railroad and the U.S. Navy. Chugach specializes in facilities operation and maintenance for clients such as Alyeska Pipeline Service Co. and the U.S. Department of Labor.

"We're bringing our particular expertise to Chugach's portfolio of services," said William Weinstein, executive vice president of Emerging Technologies. "They're bringing us financial backing and the ability to compete as a minority contractor for federal contracts."

Chugach Development is a wholly owned subsidiary of Chugach Alaska Corp., said Dusty Kaser, executive vice president of CDC. Chugach Alaska is a holding company owned by 1,900 Aleut, Eskimo and Indian people. Total revenues for the corporation last year were $34 million. It employs about 550 people.

Emerging Technologies consists only of Weinstein and partner Ken Garrett. Weinstein declined to disclose his company's sales volume.

Kaser said Chugach Development is an environmental services contractor that does a large share of its business in what are known as base service operations. Such companies act as contractors that handle a broad range of operations and facilities maintenance services. Those services may range from simple building maintenance to paving roads.

"We go in and do what ever needs to be done at a facility," said David Maiero, Chugach Development division manager.

A well-known local example of how such contractors function occurs at the Hanford Nuclear Reservation, said Maiero. While Westinghouse Corp. subcontracts many of its functions there, it remains the master contractor with the federal government for the facility's maintenance and daily operations.

Chugach was interested in pursuing a joint venture with a remediation firm because environmental work is increasingly being added as a maintenance function for such facilities contracts, said Maiero.

Continued on page 17

Motif retrofit cost soared beyond $2 million

By RACHEL ZIMMERMAN

Reports that Motif Inc.'s failed liquid crystal display manufacturing plant would have cost $2 million to fix are unrealistically low, according to industry analysts, who say it would likely cost five times that amount to alleviate problems on the pro-

Motif Inc., a 2-year-old joint venture of Motorola and In Focus Systems, Inc., announced Oct. 13 that its Wilsonville factory, which produces liquid crystal display screens, would shut down, putting 45 people out of work. However, Motif will continue to manufacture integrated circuits for

Deal with Chugach brings additional cleanup opportunities

[redacted] The Alaskan firm settled on Emerging Technologies because of the 2-year-old company's record of success. "These folks have what a lot of other companies in their field don't have and that's a real track record," he said.

Emerging Technology's Weinstein and Garrett pursued the relationship with Chugach because each was familiar with the company from time they spent working in Alaska, said Weinstein.

The partners originally met in 1989 during the infamous Exxon Valdez oil spill in Prince William Sound. Weinstein was city manager for Cordova, located at the eastern inlet of the sound. Garrett was brought in by Exxon to head its cleanup operations.

While Garrett was researching various means of dealing will the mess, he came across a technology under development in Russia that modified natural bacteria to speed up the natural biological degradation process.

Living in Alaska, Weinstein had made numerous Russian contacts already and the pair decided to go into partnership. They opted to site the business in Portland because of its central location on the West Coast. "Besides, Kenny's from Oregon and his family is here," said Weinstein.

But the unusual cleanup technology proved slow to sell to clients unfamiliar with the way it worked. "We've done projects for free just to prove the technology works," said Weinstein.

Bioremediation of the sort Emerging Technologies employs has become increasingly accepted in environmental cleanup circles, said Bob Rodman, senior environmental engineer with Pacific Western Services in Silverdale, Wash. "The sheer economics of it have given people the nerve to try it out," said Rodman. "It can cost you half what some of the alternative techniques do."

Alternatives include hauling soil offsite to a landfill, or taking it to a special facility where it is heat-treated and then returned to the original site.

Rodman hired Emerging Technologies to clean up gasoline spilled by a leaking pipe at Bangor Naval Submarine Base in Washington state. "They actually cleaned up a site that was underneath the pavement without ripping anything apart," said Rodman.

Motif shares technology with Japanese

Continued from page 4

closure costs. "We just decided the LCDs were not strategic for either company," Harker said.

Shawn Willard, an analyst with the Charter Investment Group in Portland, estimated the price of necessary improvements at Motif would be close to $10 million.

"It was a good idea to shut it down," said Willard, citing tremendous competition in the LCD market, which is dominated by Japanese manufacturers.

Sharon VanSickle, a spokesperson for In Focus, agreed that the cost of improvements would have surpassed $2 million.

Motif reached agreements with four other companies—one in the United States and three in Japan—which will purchase its active addressing technology: Standish, Sanyo, Kyocera, and Optrex.

In another development, In Focus is forging ahead with a separate joint venture with the David Sarnoff Research Center in Princeton, N.J. The new company, Sarif Inc., will produce polysilicon active-matrix flat panel displays and tiny, high-resolution, color "image engines," to be used in projection systems.

Steven Hix has stepped down as chairman of the board of In Focus to become chairman and chief executive officer of Sarif. The move, said Harker, in no way represents a demotion. "This is a great move for Steve," said Harker. "It's the opportunity of a lifetime."

Kenneth Garrett (left) and William Weinstein are pinning their hopes on this $4,000 container of pollution-eating microbes.

Secret compound looks like pollution buster

ETA Gresham corporation is opening eyes with its ability to clean up waste in soil and water both economically and quickly

By ERIC GORANSON
of The Oregonian staff

William Weinstein and Kenneth D. Garrett figure they can clean up much of the world a pollution problems a lot quicker and cheaper than anyone else

And they claim they can do it with a secret Russian compound they are importing in 5-gallon jugs

Garrett, a native of Baker City and oil cleanup expert, lives in Gresham; Weinstein, a native of Georgia, resides in Portland. Their corporation, Emerging Technologies International, operates out of Garrett's home, uses a post office box on Southeast Foster Road. They hope Weinstein said to move into a "green urine" office soon

Most people and corporations Weinstein said are skeptical, especially when they are told the product is imported from Russia But, to date, the company has delivered the goods on a handful of minor cleanup jobs

And the fledgling two-man conspiracy has the lofty potential of garnering as much a $6.5 million in soil and water cleanup work in the next few years, Weinstein said, showing a list of in-hand and potential jobs

A major portion of the work could come from an agreement with Chugach Development Corp., an Alaskan native company that has, Weinstein said, the environmental cleanup contract with the U.S. Navy in Alaska

"We've spent 18 months in missionary work and research and development," Weinstein said "No one first believed us. We even did a job for the Port of Portland free to show what we could do"

The two men met when the Exxon Valdez spilled million of gallons of crude oil into Prince William Sound creating the nation s worst environmental disaster Weinstein was an interim city manager for Cordova Alaska, Garrett was head equipment manager for Exxon during the cleanup

Though on opposite sides in the cleanup battle, they became friends and figured if they could come up with something that cleans up soils and waters better there would be a ready market for the product

Garrett, 39, had worked on the Alaska pipeline and in environmental work at Prudhoe Bay Weinstein, 40, had transferred to a federal Housing and Urban Development job to Anchorage in 1980 from North Carolina and subsequently held several jobs until moving to Cordova

After the Exxon Valdez cleanup

> *"No one first believed us. We even did a job for the Port of Portland free to show what we could do.*
>
> William Weinstein

Weinstein visited the Soviet Union with hopes of starting a business exporting some of Siberia's coal or oil to America. Instead, he said, he wound up meeting Russian scientists and returned to Alaska with a microbe called Lyrohalized bacteria.

Vladimir N. Diadechko of the Tyumen Institute of Oil Geology had developed the bacteria to clean up petroleum-contaminated soils

Use of hydrocarbon or petroleum eating microbes to clean polluted soils was nothing new to American scientists, but what the Soviets had developed was one that worked faster than anything around and cost less

What they did, Weinstein explained was to remove enzymatic compounds and biosurfactants — "the cream of the culture that degrades the hydrocarbon — from the bacteria and make them into a liquid

The Soviet government, Weinstein said, didn't know of the technology "I suspect" the researchers "stumbled on it by accident.

"No one can patent bacteria, and it would be extremely difficult and take years for someone here to isolate the culture," he added

Garrett, meanwhile, became a consultant for VECO Inc. and worked in Saudi Arabia, cleaning up the deliberate Kuwaiti oil spill by Saddam Hussein.

When both men returned to Alaska they decided Portland would be a more central location to set up a business to serve the West Coast

Incorporated in 1992 in Oregon ETI began working the process, calling on companies, sending out samples of the compound to drum up business

One of ETI's first projects was for Samuam Memorial Hospital in Stayton

The hospital discovered it had a soil and ground-water contamination problem when it began an expansion project. The polluted water was extracted and placed in a 20,000-gallon tank and the biosurfactants added

"We were very skeptical," said Terry L. Fletchall, hospital administrator, "but ETI was looking for recognition and was willing to do the job for far less so we took a chance."

Seven days later the water was clean enough to discharge into the city s sewer system. The cost to Samaritan was about one-third it would have otherwise cost, Fletchall said.

In January, ETI cleaned up contaminated soil on the site of a former Shell Oil service station that was razed to make way for the Portland Trail Blazers new arena.

ETI piled up the soil over large perforated pipes, pumped air into the pipes and twice sprayed the pile with water containing their petroleum-eating compound

Fifty-nine days later the soil was clean. It was faster than expected since it was cold and the biosurfactants work best when it is warm Weinstein said

The traditional cleanup method of hauling the soil away heating it to burn off the hydrocarbons and returning it would have cost three times as much, estimated Robert L. Collier, Trail Blazer senior project manager

S.J. Parker, head of A.J. Dani Construction Co.'s environmental cleanup division in Santa Maria Calif., didn't believe ETI's claims initially, but now he uses its compound on several jobs

"I'm amazed," Parker said. "Other cleanup agents leave water murky this leaves it clear and does it so quickly, it's incredible."

Parker said he maximizes the compound being used to clean the air and so a fire suppressant. Gasoline wouldn t ignite after being sprayed with the compound, he said.

As for those other uses, there just hasn't been enough time to get into them, Weinstein said

Company uses microbe to clean contaminated dirt

Two entrepreneurs utilize the process at Oregon Arena. Blazers' new home

by JOE FITZGIBBON

Two entrepreneurs have found a way to combine Russian technology and American know-how to clean up contaminated soil at the new Oregon Arena.

William Weinstein and Kenneth Garrett, co-owners of Emerging Technology, injected freeze-dried microbes known as Lyophilized bacteria into petroleum-contaminated soil. The contaminated dirt was left over when Rav's Coliseum, Shell property was sold to the Portland Development Commission for the future home of the Portland Trail Blazers.

Natural enzymes in the bacteria will gobble up petroleum contaminants, leaving 3,200 cubic yards of dirt well within the Oregon Department of Environmental Quality mandate for remediation.

"It's the first time I've seen this technology in action," said Bob Collier, project manager for the Oregon Arena. "But it's going to be good for the environment and cost-effective for us."

James Anderson, environmental coordinator with the PDC, said that the proposed $25-a-cubic yard remediation cost promised by Emerging Technology is half of the "burn and return" expenditure originally planned for the soil.

Previously, PDC sent truckloads of the contaminated soil to Oregon Hydrocarbon, where the petroleum was burned off in huge kilns at temperatures in excess of 800 degrees Fahrenheit, then returned to the Arena for use as backfill.

International reputation

But some environmental risks and costs — more than $50 a cubic yard in truck transportation — prompted Anderson to try bioremediation.

"I knew Weinstein and his partner could deliver on their promises from earlier projects they had success with," Anderson said. "They're the leading edge in this technology and fit our goals to construct the Oregon Arena using environmentally sound principles."

According to Anderson, Emerging Technology's contract falls well within the $25,000 set aside from Oregon Arena's $40 million budget for environmental projects. Still, PDC has asked Shell Oil Co., the original owner of the property, to pay remediation costs.

Weinstein and Garrett earned an international reputation after the Valdez oil spill and the Persian Gulf War for their experimental use of bioremediation. They discovered its practical use while visiting Russian scientists in the Tuman Pectura region of Siberia. In spite of a language barrier, the two men were the first Americans to enter some of research centers.

"The first thing we had to do was earn their trust," Weinstein said. For years, no one — not even their own citizens — had been allowed to step foot in some of these areas.

Scientists showed them natural strains of bacteria they were using to clean up scores of oil and gasoline spills throughout the region.

Weinstein and Garrett entered into a joint agreement to bring back the technology and several former Soviet Union scientists to Oregon to create bacterial strains that can work in temperatures from minus 32 degrees F to as high as 122 degrees F.

Scientists in Russia have created cultures from the natural bacteria then removed the enzymatic compounds and biosurfactants — or what they call the "cream of the culture" — and freeze-dried them into a powdered form. They send the inert material to Portland, where technicians rejuvenate the microbes with a warm liquid solution.

Complete elimination

The first step in the cleanup calls for adding the biosurfactants to the contaminated soil to crack open the molecular chain of the hydrocarbon. The petroleum-hungry microbes are then released into the soil to gobble up the petroleum in two to four weeks, they die off, leaving only carbon dioxide and water as byproducts of their feast.

Preliminary tests from the Arena site showed complete elimination of petroleum in five of the seven samples that were taken.

"People have a tough time believing it's this simple, until they see the results," Weinstein said.

Emerging Technology has successfully treated contaminated sites throughout Oregon, including jet fuel spills at the Portland Air Base and diesel cleanups with several local companies.

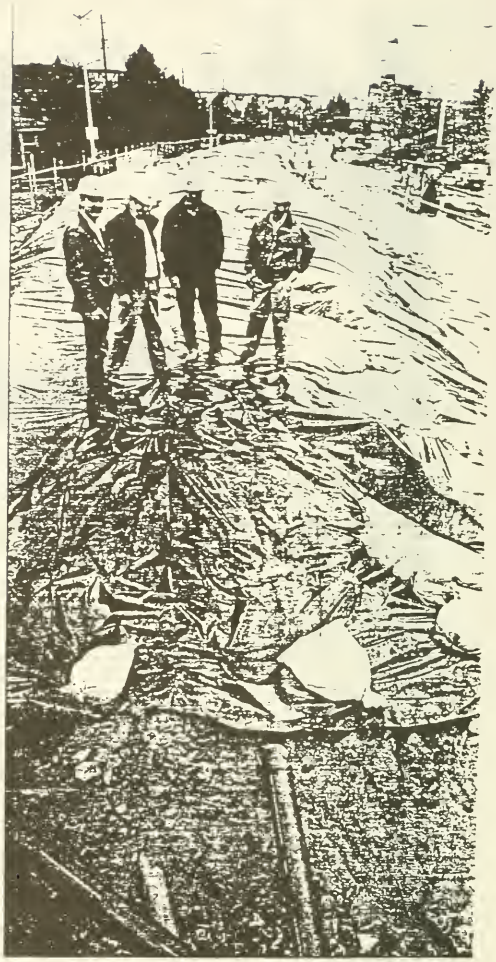
"We've done a lot of pilot projects — actually more like missionary work — to convince people of the success of this technology," Garrett said.

Garrett and Weinstein said that the only problem they have encountered with the tons of soil spread out near North Interstate Avenue has been Portland's rainy weather. They have used plastic tarp to hold back the showers and keep the microbes supplied with warm air through a network of pipes placed 4 feet into the soil.

"There is really limited maintenance to this process," said Weinstein, standing atop the small mountain of soil. "Because we laid the soil out flat and kept it on site, we are well ahead of our February schedule."

When the men finish the Oregon Arena project, they plan to apply their technology to cleanup projects for the U.S. Navy and several petroleum distributors in California.

They said that they also have discovered three strains of bacteria that are successful in biodegrading chlorinated solvents such as those found in household cleaning fluids.



JOEL DI

Looking over a project that is using microbes to clean up petroleum-contaminated soil at the Oregon A struction site are (from left) Kenneth Garrett, Bob Collier, William Weinstein and August Sestrap.

velop joint research ventures between Russian and American universities and businesses in environmental cleanup technology.

Oregon could become the nation's center for environmental research in the United States, Garrett said. "There is a rapidly growing interest in biotechnology exchange among nations and we want to bring this microtechnology and its application to commercial markets."

Recently, a curious passerby wanted to know if microbes in the soil make any noise while devouring petroleum or if they can escape into the streets. No, was the answer. "We've heard it all," he said with a laugh. "OK," he said with a laugh, "have asked the same question years ago."

Joe Fitzgibbon is a staff writer based in Portland.

service, and retains international patents and trademarks for key markets. The joint venture also uses Berger's own accountants because he found Japanese accounting "antiquated and mysterious." And because Berger heard that Japanese business is driven by market share — not income — beginning in 1994 Rentrak Japan Ltd will pay Berger's Rentrak Corp. 1.67% of the joint venture's sales.

"Such joint ventures are always a good idea if you're entering a new market where you have absolutely no expertise, and feel there would be structural barriers to your entry," Berger explains. "But you must have the business and management capacity to handle the new venture. And if I had my druthers, I'd never have a venture I didn't own 51% of, because someday I may try to negotiate a worldwide deal. But due to the joint venture, I may not be able to guarantee a market in Japan, and may have to negotiate with CCC. Still, could I have gotten to this point without it?"

Carl Wilcox believes successful international joint ventures require building solid relationships

But this "international firm finds Oregon partner" scenario is unusual, so most expansion-minded Oregonians must hit the joint-venture-finding trail.

Keith Erickson, director of Pacific Rim operations for Boise-based Trus-Joist MacMillan (TJM), says his firm had to interview eight Japanese firms in 1983 before choosing Taihei Machinery Works Ltd. to manufacture laminated veneer machinery designed by TJM.

Yet after just three months of negotiation, the companies agreed that TJM would design — and Taihei manufacture — the equipment. And the joint venture would handle sales and distribution, primarily in Asia.

TJM shielded proprietary information through patents, contracts and technology transfer protection that extended beyond the life of the agreement. A tight exit strategy guaranteed a long-term relationship.

Unfortunately, they never sold a machine. The partnership succeeded, however, and Taihei makes other equipment that TJM sells in the United States and Canada.

Revolutionary technologies. Perhaps more challenging is the story of Emerging Technologies, based in Portland. Deterred from early plans to export natural resources from Russia to the United States, the company instead secured exclusive marketing and licensing rights for several revolutionary Russian technologies from the scientists who created them. Some of these inventors never revealed their discoveries to the former Soviet government. Now they want them commercialized in the West.

Emerging Technologies has taken the first steps toward true joint ventures between its clients in the United States and Russia. It's tricky in such a volatile country.

Because there are no private Russian firms to deal with, agreements hinge on the friendships partners Kenneth Garrett and William Wemstem have with the Russian scientists.

"When doing business in Russia, it doesn't matter how big your U.S. company is," Wemstem says. "If you don't build appropriate personal relationships, they won't do any business with you."

Emerging Technologies' first products are a surfactant and a natural bacterial preparation that cleans hydrocarbon-contaminated soil and water. Wemstem plans to secure Wall Street funding to develop Russian pharmaceutical, laser, water purification, microwave and possibly military technologies. In addition, the firm links Russian scientists with counterparts in the United States.

Yet some international joint ventures flop. A prime example is the renowned Intel-Siemens Group arrangement from the late 1980s.

"We got to a concept and a general category of computers, but couldn't find a market," explains Bob French, Intel's manager of public affairs.

Obviously, international joint ventures don't work for everyone. Big players, like Nike, avoid joint ventures in favor of distribution or licensing agreements and wholly-owned subsidiaries.

Most smaller firms must create joint ventures to enter these diverse international markets, and they have to tread carefully. They must lead from strength, know their strategic needs, know their partners, hire consultants with in-the-field experience in the targeted country and protect their technologies.

Many will get help from *International Joint Ventures: A Practical Guide*, written by John Karalis, vice president of corporate development and secretary of Tektronix.

"We Americans expect it to come easy," Erickson notes. "But in my eight years in international trade, I've found the biggest difference between the U.S. and other countries is patience. If you get in and work hard with the system, in most cases you'll work through cultural, economic and political barriers." ■

To receive by fax a list of international trade resources, please call 1-800-553-3299 and use Datafax Code #126.

EPA Environmental Technology Initiative Proposal Cover Sheet

1. Project Title: Environmental Center of Excellence for the Promotion of Information and Innovative Technology Transfer and Export within the United States and to Pacific Rim Countries.

2. Abstract:

The environmental information systems and innovative technology (IS/IT) developed by the EPA Superfund Program represents a significant national investment. The effective export of regional and national IS/IT is dependent on building an effective marketing infrastructure involving Oregon large and small businesses, state government and federal agencies. An Environmental Center of Excellence will accomplish three interrelated goals: (1) transfer of IS/IT to Oregon state agencies and small businesses, (2) testing and development of innovative technologies to remedy point and nonpoint source pollution; and (3) marketing of IS/IT to Pacific Rim countries by small businesses.

3. Keywords: innovative technology, information systems, technology outreach, technology demonstration and evaluation, technology diffusion, Pacific Rim countries, technology transfer

4. Topic and Major Focus Area: Innovative technology and information system transfer to Oregon state agencies and small businesses for the promotion of marketing of local and national environmental technologies in Pacific Rim Countries

5. Total Project Budget	**6. Amount Requested From ETI**
$ 910,000	$ 750,000
7. Submitting Organization and Contact Person: Oregon Department of Economic Development 121 SW Salmon St., Suite 300 Portland, Oregon 97204 Contacts: Mr. William Scott Ms. Janet Jones	**8. Major Partners:** Oregon Environmental Technologies Association P.O. Box 672 Portland, Oregon 97207-0672

Shaded Area For EPA Use Only

9. Date Received	**10. Proposal Number**

11. Committee Assignment

12. Comments

1.0 BACKGROUND

Oregon is a state with a long history of environmental protection. Because Oregon is out of the mainstream of national environmental policy development, but has been a leader in small business innovation in the environmental field, there has been an historic need to facilitate information transfer between EPA, Oregon state agencies, and large and small business. In addition, Oregon is in an uniquely strategic position to accelerate export of both regional and national information systems and innovative technologies (IS/IT) to Pacific Rim nations. The creation of an Environmental Center of Excellence will act to catalyze export of IS/IT and promote sustainable development in these targeted countries.

1.1 STATING AND ADDRESSING THE PROBLEM

Problem 1: Inadequate transfer of information from national EPA resources to small businesses in Oregon and the Pacific Northwest.
Guidance documents and database resources developed by various EPA divisions and laboratories represent a significant national investment and resource. These guidance documents and innovative technology transfer programs have had a significant beneficial effect on remedying environmental problems at Superfund, Department of Defense (DOD), and Department of Energy (DOE) sites. Furthermore, contaminated sites at federal properties regulated by EPA have served as test cases for innovative cleanup of contaminated materials. However, this information has not been readily transferred or applied to environmental problems regulated by state agencies. Often, information that could be useful to a state-regulated problem is not readily available in a format that can be used by the state agencies. As a result, states consume valuable resources responding to environmental questions, building databases, and testing policies and technologies when much of this information is already readily available.

Approach 1: Creation of Center of Excellence for Information System and Technology Transfer (Center)
Environmental problems require site-specific remedies. One focus of the proposed Center will be the appropriate application of EPA national guidance, databases, and innovation technologies to Oregon-specific problems. The Center will provide an outreach program that combines three component programs: (1) training, (2) partnering of small and disadvantaged business with national environmental contractors, and (3) partnering of government and industry sectors in each country. A primary focus of the Center will be to educate citizens and contractors on the rationale that drives environmental regulation and cleanup for activities such as is provided by human and ecological risk assessments. In addition, the Center will serve to facilitate teaming possibilities between small and large environmental businesses at DOD and DOE sites.

Problem 2: National Innovative Technologies Do Not Target Oregon-Specific Environmental Problems
National innovative technologies programs do not address specific environmental problems of Oregon and the Pacific Northwest. For example, EPA helps to remedy hazardous waste and point source problems under the Superfund Innovative Technology Program (SITE). However, the national SITE program does not always address remediation of problems specific to Oregon, such as nonpoint source pollution. In addition, Oregon is at the center of the development of bioremediation technology, which has yet to reach its full application or market potential. Dissemination of Oregon-based technology to DOD and DOE lags behind other states. For example, though Hanford is only miles from Oregon and, in fact, the Columbia River is the major exposure pathway of Hanford contaminants, only 3 percent of the budget for hazardous waste cleanup at the Hanford Nuclear Reservation went to Oregon businesses in Fiscal Year (FY) 1993.

Approach 2: Create an Innovative Technologies Center for the Pacific Northwest
The Center should have the facilities to test innovative technologies at contaminated sites in the Pacific Northwest. The Center will focus its efforts on technologies designed specifically to remedy problems associated with the unique ecology of the region, but that also can be applied nationally.

Problem 3: Innovative Technologies and Oregon Environmental Resources are not Exported to Their Fullest Potential to Pacific Rim Nations and Domestically to Significantly Contaminated DOD and DOE sites

Currently, the transfer of EPA IS/IT to State agencies and the small business sector has been very slow. As a result, the marketing of IS/IT by small business to domestic and international clients has also been sluggish. The essential problem faced by Oregon small business is one of penetration of internal and external markets. The markets can only be penetrated by effective teaming of small businesses, large businesses, state government, and federal agencies.

Approach 3: Create and Add to the Existing Infrastructure for Marketing of Regional and National IS/IT
An environmental remedy, information system, or database is successful only if it is used. While Oregon can clearly provide unique resources to a national marketing strategy, these resources have not yet been mobilized effectively. The Center will facilitate small and large business teaming arrangements, which will provide a more marketable product as large businesses provide market access to smaller businesses. Small businesses can provide the innovative technologies necessary for a competitive edge.

1.2 PROJECT HISTORY

This purpose of this project is to fill a significant gap in the existing infrastructure. For years, the name of Oregon has been syoonymous with environmental protection. Many of the most significant environmental problems facing the United States are being investigated and tested in Oregon. However, the information transfer between EPA and both public and private sectors in Oregon has been inadequate. These issues as well as the lack of true remediation at the Hanford Nuclear Reservation, has led to intense discussions in Oregon environmental community. The concept of an Environmental Center of Excellence to inform and facilitate technology transfer is a product of those discussions.

1.3 PROJECT APPLICABILITY TO SELECTION CRITERIA

Table 1 identifies applicable project-specific and general selection criteria identified in the ETI solicitation package and explains how the proposed project addresses each criterion.

TABLE 1 - SPECIFIC SELECTION CRITERIA RELEVANT TO THE PROPOSED PROJECT

SELECTION CRITERIA	PROJECT RELEVANCE
APPLICABLE PROJECT-SPECIFIC CRITERIA	
A. Policy Framework	
A.2.1 Complementary Nature of the Project	This project will facilitate transfer of the EPA policy framework and innovative technologies to Oregon-specific problems such as non-point source degradation of watersheds. Thus, for example, this goal will allow complementary application of guidance from CERCLA programs to Clean Water Act programs.
A.2.2 Extent of Impact	The results of the project will impact both federal, state and regional-levels of government. The project will act as a catalyst to improve environmental protection at all levels of government.
A.2.3 Ability to Produce Needed Results	The project is a partnership between industry (OETA) and state government (OEDD) in conjunction with the EPA. In addition, the Center is endorsed by the State's congressional delegation, which is dedicated to the success of the project's goal.
A.2.4 Reduction of Barriers	The product of this project will be an effective partnership between large and small businesses, facilitated by governmental agency input, that permit a more effective marketing of environmental services.
B. Innovation Capacity	

SELECTION CRITERIA	PROJECT RELEVANCE
B.2.1 Project Emphasis	The project supports small business and small communities.
B.2.2 Sustainability	The project requires a short-term funding source, but will be sustainable by private resources in the long-term.
B.2.3 Environmental Technologies	The project will strategically support remediation technologies through its program for site-specific testing and development of technologies marketed by small businesses.
C. Environmental Technologies	
C.2.1 Substantial Advance in Performance Over Conventional Technology	The Center will test innovative technologies on a site-specific basis and provide the rationale for use on regional projects thus facilitating the development and commercial success of innovative technologies, particularly the various forms of bioremediation currently being developed in the Pacific Northwest.
C.2.2 Low-Cost, Low-Maintenance Technologies	The focus of the Center will be on the testing of in-situ and ex-situ remedies for organic and inorganic contamination of soils and groundwater as well as remedies for nonpoint source pollution.
C.2.3 Multimedia, Multipollutant, and Multi-Industry or Sector Technologies	The project will test and develop technologies that remedy point and nonpoint source pollution. In addition, testing and development of bioremediation technologies will be an important component of the Center.
C.2.4 Ready for Later Stages of Development	Many of the promising remediation technologies currently available have been demonstrated to be successful contaminant- and site-specific methods; these methods can now be applied to new problems.
C.2.5 Identification and Participation of the Customer	The customers in this project include partners in OETA, DOD and DOE, and potential customers in international markets. A key strategy in this project is the formation of effective teams to penetrate key markets using the complementary strengths of large and small businesses.
E. Domestic Diffusion	
E.2.1 Customer-Based Project Design	OETA will act as the lead for this project. The participation of 40 to 50 environmental firms in Oregon is anticipated. Testing innovative technologies onsite will ensure a customer-based project design.
E.2.2 Supports Small Businesses and Small Communities	The expressed purpose of this project is to facilitate teaming arrangements between large and small businesses to introduce their products into previously impenetrable internal and external markets.
F. International Diffusion	
F.2.1 Federal, State, Local Government, and Not-for-Profit Organization Involvement	Project partners include state and private industry organizations.
F.2.2 No Duplication with Existing or Ongoing Programs	There are no current projects, assistance, or funded mechanisms that duplicate the goals of this project.
F.2.3 Supports Nation's Environmental Goals	A primary outcome of this project will be the achievement of public health risk reduction and ecosystem protection through remediation of point and nonpoint source pollution.
F.2.4 Clear Identification of Resources and Timeframes (Short- and Long-Term)	Project partners have been identified and roles have been defined; up-front planning and coordination will ensure attainment of short-term goals within one year, which will position the project for continued long-term success.

SELECTION CRITERIA	PROJECT RELEVANCE
F.2.5 Actual Demonstration of Innovative Approaches	The Center will work directly with facilities to implement and test innovative technologies; the project will focus on technology demonstration rather than technology identification.
F.2.6 Creating Public-Private Sector Partnerships	International government and industry partnering is a critical success factor for the proposed project.
F.2.7 Leveraging of Matching Funds and In-Kind Services	The project will receive $ 160,000 in support from OEDD and OETA for the first fiscal year.
F.2.8 Relationship to Common Sense Initiatives	The central focus of the proposal, which is to facilitate and disseminate the marketing of IS/IT by small businesses, is directly applicable and in every real sense embodies the essence of the common sense initiatives.

2.0 PROJECT DESCRIPTION

2.1 PROJECT GOAL

The short-term goal of the project is to create an Environmental Center of Excellence in Oregon to facilitate the transfer of IS/IT from national EPA resources to small businesses within Oregon thereby allowing them to compete more effectively nationally and internationally. The immediate goal of the project will be the creation of a computer network to facilitate information transfer between EPA and OETA. OETA will compile the environmental expertise and resources of Oregon environmental, construction, and engineering firms to determine possible teaming partnerships. In addition, OETA will identify promising technologies in the latter stage of development that have multiuse capabilities and can be tested on contaminated sites in Oregon.

Long-term goals of the project will include the identification and harnessing of resources of the state government and OETA that can be leveraged to create marketing strategies for large and small business teams, both in domestic and international markets. The final goal of the project will be a self-sustaining Environmental Center of Excellence that facilitates the export of environmental technologies from Oregon to domestic and international markets. The dissemination of IS/IT by small businesses will by itself help to achieve the common sense initiatives put forward by the EPA.

2.2 PROJECT TASKS

Task 1: Promote Diffusion of EPA IS/IT Through the Creation of an Environmental Center of Excellence.
The Center will be operated by Oregon Economic Development Department (OEDD), but will be managed and staffed by OETA. OETA will develop an interactive database that compiles relevant EPA initiatives and guidance. This network will be provided to OETA members as an on-line service. In addition, OETA will develop short courses and appropriate training for OETA members to improve the competitiveness of Oregon small business for domestic and international clients.

Task 2: Evaluate, Document, and Demonstrate the Performance of Regional Innovative Technologies.
OETA will solicit proposals for innovative technologies to be tested at contaminated sites in Oregon. Industry representatives participating the Oregon Department of Environmental Quality Voluntary Cleanup Program will be encouraged to participate in the Center's activities.

Task 3. Large Business/Small Business Initiative.
The Center will facilitate large and small business teaming arrangements and provide information on proposals and markets for those teams. The Center will begin providing workshops and seminars on the IS/IT products and methods to penetrate internal and external markets.

Task 4. Build Capabilities within the OEDD Infrastructure to Promote Domestic and International Marketing of IS/IT.
One of the first tasks of the Center will be to determine domestic and international areas that OETA members have penetrated and determine which small business products are most appropriate to market in those areas. The Center will serve as a clearinghouse for business leads and proposals for Oregon small businesses.

2.3 SCHEDULE OF ACTIVITIES

Table 2 presents the proposed task schedule and timeline. The proposed project has been forecasted for a one-year time period.

TABLE 2 - SCHEDULE FOR DEVELOPMENT OF THE ENVIRONMENTAL CENTER OF EXCELLENCE

ACTIVITY	TIMELINE
Project begins with the creation of Environmental Center of Excellence at existing OEDD/OETA facilities	January 1, 1995
On-line support information system in place	January 21, 1995
First solicitation for innovative technologies.	February 1, 1995
First small business training workshop on EPA information systems	February 10, 1995
Selection of innovative technologies to be tested in 1995	March 21, 1995
Large and small business teaming initiative.	April 15, 1995
Testing of first innovative technologies demonstration projects	May 1, 1995
First training of OEDD, OETA and state agency personnel on marketing of environmental technologies	June 1, 1995
Six-month progress report	July 1, 1995
Second solicitation of innovative technologies	August 15, 1995
Development of IS/IT newsletter and success stories	September 1, 1995
Matching fund initiative	September 1, 1995
First Environmental Center for Excellence technical and trade conference on IS/IT	October 15, 1995
First international teaming proposal complete	November 15, 1995
Annual report	December 21, 1995

2.4 BUDGET AND MATCHING FUNDS

Table 3 shows the one-year budget for the Environmental Center for Excellence. The project will require a budget of $ 910,000. OEDD and OETA will provide in-kind services worth an equivalent of $ 160,000.

TABLE 3 - PROPOSED ESTIMATED BUDGET

TASK	REQUESTED ETI FUNDS	IN-KIND SERVICE	TOTAL PARTNERS CONTRIBUTION
Environmental Center	$ 230,000	$ 25,000	$ 255,000
Innovative Technologies	$ 310,000	$ 50,000	$ 360,000
Large business/small business team initiative	$ 120,000	$ 35,000	$ 155,000
Infrastructure building	$ 90,000	$ 50,000	$ 140,000
TOTAL	$ 750,000	$ 160,000	$ 910,000

3.0 QUALIFICATIONS

3.1 EXPERIENCE OF PARTICIPATING ORGANIZATIONS

Oregon's OEDD is a state agency with a primary mission to create jobs and stimulate Oregon's economy. The Environmental Center for Excellence will work with OEDD's Key Industries Program and the International Trade Division. The Key Industries Program helps Oregon industries become more competitive and one of the targeted industries is environmental services. The program promotes strategic partnerships among industry, education, research organizations, and government. The International Trade Division assists Oregon companies wishing to access foreign markets, especially in the Pacific Rim. It also maintains offices in Japan, South Korea, and Taiwan.

3.2 KEY PERSONNEL AND THEIR INVOLVEMENT

Rick Evans manages the OEDD's Government Contract Acquisition Program for OEDD and will be responsible for overseeing the process by which companies submit proposals to demonstrate their innovative technologies. Philip Hirsch manages the Oregon Hanford Technology Outreach Program and will be responsible for providing technical assistance on cleanup technology. Janet Jones is the Key Industries manager for OEDD. Her responsibilities for this project will include coordinating Center activities with the activities of industry/trade associations to develop markets and promote technology transfer and access. David Welsh is the executive director of the OETA. OETA will be responsible for managing the Center's activities and for conducting educational programs and outreach to environmental firms involved in this project.

3.3 EQUIPMENT AND FACILITIES

OETA has sufficient office space to manage this project. However, this project will, in the near future, require additional office space for new OETA support staff. Generally, the need for additional equipment and facilities will be minimal because the activities of support staff will rely on the existing infrastructure of OETA and OEDD.

3.4 IMPLEMENTATION AND COMMERCIALIZATION OF THE PROJECT

One goal of this project is to introduce new IS/IT to the international arena; these technologies are intended to increase the efficiency and global competitiveness of U.S. companies. Concurrent with this goal is to promote environmentally sound practices. Providing direct assistance to environmental firms will (1) strengthen the capability of technology developers, (2) accelerate diffusion of IS/IT in international markets, (3) support efforts to facilitate large and small business partnership, and (4) enhance commercialization of low-to-medium cost technologies available to the various facilities.

ELIZABETH FURSE
1st District, Oregon

COMMITTEES
BANKING, FINANCE AND URBAN AFFAIRS
Subcommittees
Housing and Community Development
Consumer Credit and Insurance

MERCHANT MARINE AND FISHERIES
Subcommittees
Environment and Natural Resources
Merchant Marine

ARMED SERVICES
Subcommittee
Research and Technology

Congress of the United States
House of Representatives
Washington, DC 20515-3701

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September 20, 1994

Carol Browner
Administrator, Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Carol:

I am writing in support of the proposal submitted by the Oregon Department of Economic Development and the Oregon Environmental Technology Association in response to the agency's Environmental Technology Initiative (ETI).

As you know well, Oregon is leading the nation in production of export-ready environmental goods and services. The Oregon Department of Economic Development (ODED) and the Oregon Environmental Technology Association (OETA) have jointly developed a proposal to build upon the West Coast's regional strength in environmental technologies and encourage partnership between federal and state agencies, small environmental technology business, and large multinational environmental technology corporations. An Environmental Center of Excellence would promote information on U.S. environmental technology goods and services, boost exports in an expanding global market, and encourage technology transfer within the United States and to Pacific Rim countries.

I've enjoyed our conversations in the past regarding the importance that environmental technologies will play in the future of our nation's economy. I believe ODED and OETA's submission meets and exceeds the goals of the agency's Environmental Technology Initiative, and urge your swift approval of their proposal.

With best wishes, I remain,

Sincerely,

Elizabeth Furse

Elizabeth Furse
Member of Congress

NEIL GOLDSCHMIDT INC.

October 11, 1994

Mr. David Gardiner
Assistant Administrator
Office of Policy, Planning and Evaluation
Environmental Protection Agency
Mail Code 2127, Room M 3006
401 M Street SW
Washington, DC 20460

Dear Mr. Gardiner:

I am writing in support of the Environmental Technology Initiative proposal submitted by Oregon Economic Development Department and Oregon Environmental Technologies Association. The proposal is to create an Oregon Center of Excellence to develop and disseminate advanced environmental remediation technologies.

Oregon has a history of environmental concern, a strong and growing environmental remediation industry, and recent technology transfer efforts. The Center of Excellence in Oregon can build on this foundation to further applied research and business development in the field of environmental remediation.

Sincerely,

Neil Goldschmidt

MARK O. HATFIELD
SPECIAL DISTRICTS CENTER
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SALEM, OREGON 97301

MARK O. HATFIELD
ONE WORLD TRADE CENTER
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PORTLAND, OREGON 97204

United States Senate
WASHINGTON, DC 20510-3701

September 19, 1994

Mr. David Gardiner
Assistant Administrator
Office of Policy, Planning and Evaluation
ETI Proposals
Environmental Protection Agency
Mail Code 2127, Room M3006
401 M Street, SW
Washington, D.C. 20460

Dear Mr. Gardiner:

I am writing today to express my support for the proposal "Environmental Center of Excellence for the Promotion of Information and Technology Transfer" submitted for funding under EPA's Environmental Technology Initiative by the Oregon Department of Economic Development and Oregon Environmental Technologies Association. It is my understanding that the purpose of a regional Environmental Center of Excellence is to adapt and promote the policy framework, information systems and innovative technologies developed by EPA over the past fifteen years in the Superfund program. Such a Center would, I believe, be beneficial to the people of Oregon in being able to adapt technologies to Oregon-specific environmental problems and to the nation in testing new remedies for non-point source problems, an area in which Oregon is already in the forefront in research and in application and remedy.

While Oregon does not have the hazardous waste problems that other states, such as Washington and California have, it is confronted with unique environmental problems which could be aided by information and policy already developed by the EPA. For example, the "Framework for Ecological Risk Assessment" has not been applied to water quality problems, such as is found in the Tualatin River and which are one of the most significant environmental problems facing the state. An Environmental Center of Excellence in Oregon would have the added benefit of applying EPA guidance to new areas and environmental problems that could expedite cleanup of existing contaminants and protection of existing resources.

Oregon has a burgeoning environmental industry which is developing markets in the rapidly developing countries of the Pacific Rim. The Environmental Center of Excellence would promote export of innovative technologies and existing policy to these countries. It would facilitate small and large businesses in advancing innovative solutions to address environmental problems in both at home and abroad.

There is a vital need to disseminate and apply Superfund-derived guidance and information to region-specific environmental problems. Moreover, regionally developed innovative technology needs to be tested and marketed to expedite cleanup of regionally significant sites such as the Hanford Nuclear Reservation and the Umatilla Army Depot. For the reasons stated above, I support this proposal and believe the proposed Center for Excellence would have both regional and national benefits.

With best regards.

Sincerely,

Mark O. Hatfield
United States Senator

MOH:aw

BOB PACKWOOD
OREGON

United States Senate

WASHINGTON, DC 20510-3702

September 20, 1994

Mr. David Gardiner
Assistant Administrator
Office of Policy, Planning and Evaluation
Environmental Protection Agency
Mail Code 2127, Room M 3006
401 M Street SW
Washington, DC 20460

Dear Mr. Gardiner,

This letter is to express my support for a proposal being submitted to the Environmental Technology Initiative by the Oregon Economic Development Department and the Oregon Environmental Technologies Association. The proposal is to create a "Center of Excellence" in Oregon to promote the development and distribution of advanced environmental remediation technologies. Both the private sector and government agencies in Oregon have a strong track record for innovating environmental assessment and cleanup technologies, and for exporting this capacity.

It is my understanding the Environmental Protection Agency is seeking to advance the ability to respond to problems, and has created the Environmental Technology Initiative to invest in the practical application of advanced remediation technologies. I am confident this Oregon proposal will support EPA's determination to translate scientific knowledge and capacity into action.

Oregon has a remarkable recent history of support for technology transfer in a variety of high technology disciplines. A major area of development within this movement has been environmental response techniques. A number of Oregon firms, both traditional engineering firms and new business initiatives, have become very active in this technical field in recent years.

I urge you to give Oregon's proposal full consideration. I am confident you will find in Oregon an excellent foundation upon which to further grow applied research and business development in environmental remediation. Thank you in advance for attention to my views.

Sincerely,

Bob Packwood

BOB PACKWOOD

BP/ts

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Congress of the United States
House of Representatives

ENERGY AND COMMERCE COMMITTEE

SUBCOMMITTEES
HEALTH AND THE ENVIRONMENT
TELECOMMUNICATIONS AND FINANCE
OVERSIGHT AND INVESTIGATIONS

SMALL BUSINESS COMMITTEE

CHAIRMAN
SUBCOMMITTEE ON REGULATION
BUSINESS OPPORTUNITIES AND TECHNOLOGY

JOINT ECONOMIC COMMITTEE

CO-CHAIRMAN
FORESTRY 2000 TASK FORCE

CO-CHAIRMAN
EXPORT TASK FORCE

September 20, 1994

U.S. Environmental Protection Agency
Administrator Carol Browner
401 M Street Southwest
Washington, D.C. 20460

Dear Administrator Browner:

I am writing on behalf of the Oregon Economic Development Department, with respect to their interest in the Environmental Technology Initiative Program.

As we in the Pacific Northwest continue to expand our role in the world trade market it is paramount that we provide the fledgling technology industry the necessary access to the rapidly changing export market. This project will also provide smaller technology firms the physical capability to test and develop various bioremediation techniques.

The clearinghouse approach that Oregon Economic Development Department proposes, in coordination with the Oregon Environmental Technologies Association, to deal with this highly complex issue truly gets to the heart of the informational problems that the small business technology industry faces on a daily basis.

I would appreciate it if you would please examine this exceptional proposal and afford the Oregon Economic Development Department and the Oregon Environmental Technologies Association, every consideration possible, consistent with your established policies and procedures. Should you have questions in regard to this proposal please feel free to contact Michael Campbell in my Portland, Oregon office.

With warm regards,

Sincerely,

RON WYDEN
Member of Congress

RW:mpc

OREGON
BIOTECHNOLOGY
ASSOCIATION

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E Mail: orbio@ortel.org

September 19, 1994

Mr. David Gardiner
Assistant Administrator
EPA

Dear Mr. Gardiner,

I am writing in support of the EPA ETI proposal entitled "Environmental Center of Excellence for the Promotion of Information and Technology Transfer and Export of Oregon-Based Technologies within the United States and to Pacific Rim Countries."

Our organization has several environmental biotechnology companies as members, and we see this area as an important one for development in Oregon. To that end, we work closely with the Oregon Environmental Technologies Association and the Oregon Department of Economic Development. We support their work and feel that an Oregon-based Center of Excellence would help disseminate the innovative technology being developed here.

Please let me know if we can provide you with additional information.

Sincerely yours,

Nanette Newell

Nanette Newell, Ph.D.
Executive Director

Congressional Testimony on Biotechnology
October 17. 1994

Kenneth J. Williamson, Ph.D., P.E.
Associate Director
Western Region Hazardous Substance Research Center

Director
Oregon Water Resources Research Institute

Professor of Environmental Engineering
Department of Civil Engineering
Oregon State University

I wish to thank Congressman Wyden and Congresswoman Furst for their invitation to address the issue of federal encouragement for the development of the biotechnology industry in the State of Oregon. It is a pleasure to see their interest and support in this area.

The portion of the biotechnology field of which I am particularly knowledgeable is related to the use of microorganisms to treat hazardous wastes. I serve as the Associate Director of the Western Region Hazardous Substance Center (WRHSRC). This is one of five EPA Research Centers devoted to research related to Superfund site remediation The Western Center, which is a consortium between Stanford and Oregon State Universities, has as its primary mission the development of technologies to treat hazardous wastes in-place or in-situ. Some 80% of our research funding is directed toward the use of bioremediation to accomplish this task. Bioremediation offers the hope of being easier, cheaper, and more effective than many other physical or chemical treatment methods.

This is an exciting time for bioremediation. The concerted research efforts in a large number of universities' laboratories are producing definitive results of the effectiveness of bioremediation. I would like to list some examples.

In the WRHSRC, Dr. Perry McCarty and colleagues at Stanford have optimized the bioremediation process for the treatment of chlorinated solvents like trichloroethene, often called TCE. TCE is one of the most prevalent chemicals at the over 2000 Superfund sites in the US Their process involves the growth of organisms responsible for this reaction on organic compounds like phenol or toluene with subsequent removals to level that meet drinking water standards. This winter this process will be tested on a full-scale basis at Edwards Air Force Base on a TCE plume remaining from practices of improper chemical disposal.

Other researchers such as Dr. James Gossett and his colleagues at Cornell University also have found organisms for the removal of TCE, but using anaerobic organisms. This bioremediation process holds greater potential for application to sites

with high TCE concentration or at sites were treatment is not feasible and we must depend on natural processes to degrade toxicants.

Also within the WRHSRC, Dr. Morrie Craig and myself have clearly demonstrated the ability of rumen organisms to anaerobically degrade trinitrotoluene or TNT. TNT presently contaminates over 1000 military sites within the US; the costs of remediation are estimated at over $1.5 billion. These organisms are capable of complete degradation of TNT to the harmless products of carbon dioxide, water, and ammonia.

These results are encouraging and can even be considered spectacular. Less than 15 years ago, it was commonly believed that bacteria were unable to degrade any of the compounds that I have mentioned today. We now know much more about the application of biotechnology to the bioremediation field, but there is still much to learn. What are some of the important research problems that we are face?

1. Bioremediation reactions are complex. The reactions often involve complex interactions of the compounds the organisms feed on and the compounds the organisms use for respiration. The compounds we add and the mixture of compounds present at the contaminated site often result in chemical reactions that are total unexpected.

2. Bioremediation requires the delivery of large quantities of chemical to the subsurface. The technologies to supply chemicals in the appropriate quantities and concentrations to contaminated soils or aquifers is essential. After delivery, the compounds must be effectively mixed over large areas. Presently, we just do not have effective methods to accomplish these requirements.

3. The remaining concentrations of contaminants after bioremediation are hard to predict. Regulations often require that we predict the concentrations after treatment or that the end concentrations will be below drinking water standards. With bioremediation, we often do not know what such values will be.

So, what can the federal government do to support biotechnology? First, it must be said that whatever support the federal government gives to bioremediation research at this time will be a good investment. The DoD and DoE cleanup estimates alone run over $100 billion for hazardous waste sites. We now know that many of these sites will be bioremediated or they will not be remediated at all. This is a technology for which one of the most important users with be a variety of federal agencies.

More support, however, is needed in this critical area. Many advancements are now ready for pilot-scale or field-scale testing; however, the costs of such operations are large. It not unusual to spend over $1 million on a single field test of a new technology in bioremediation.

Some specific examples of additional federal support need to be noted. First, the five Hazardous Substance Research Centers funded through the EPA by Superfund have always be underfunded. At $1 million per year, these Centers can only support about 6 research projects per year. It is such an underutilization of the immense expertise present in each of the Centers. It would simply be cost effective to fund the HSRCs at a higher level.

Next, the House of Representative could restore the funding for the Water Resource Research Institutes that was cut for the 1995-96 fiscal year by 25%. Over one-half of the research projects in the Oregon Water Resources Research Institute this past year were devoted to bioremediation research. Our planned research was to be immediately transferred to an Oregon consulting firm to increase their competitiveness in national and international markets. Such research will now have to be foregone because of these budget cuts.

Lastly, Congress should give serious consideration to the National Institute of the Environment initiative. The support for environmental research has for too long been too little and too fragmented. Over my 20 years of doing environmental research, I have had funding from over 10 different federal agencies. Such fragmentation results in serious duplication and a lack of comprehensive planning. It is time to consolidate our efforts into one agencies that can set environmental research priorities and direction.

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October 17, 1994

TESTIMONY OF JERRY YUDELSON

BEFORE THE HOUSE SMALL BUSINESS COMMITTEE

FIELD HEARING ON BIOTECHNOLOGY

1. INTRODUCTION

My name is Jerry Yudelson, and I am the president, CEO and founder of World Envirotech Services & Technologies, Inc., Portland, Oregon. I founded World Envirotech one year ago to commercialize environmental biotechnology for both domestic and Asian-Pacific markets. Our company currently has seven employees. Since our founding we have focused on biofiltration technology, a method for treating gaseous or vapor-phase contaminants by passing them through a filter medium containing various colonies of micro-organisms. U.S. research over the past five years and European experience over the past ten years have shown that biofilters can be nearly 100% effective in reducing contaminants, such as petroleum hydrocarbons, to harmless substances such as carbon dioxide, water and inorganic salts. Cost savings can total 30% or more over the best current technology.

2. MARKET POTENTIAL

The U.S. market potential for products based on biofiltration is nearly $1 billion by the year 2000. This translates roughly into the potential for 20,000 jobs to design, manufacture, install and service these technologies. Markets which can be served include environmental remediation (including Superfund sites, military bases and the Hanford cleanup), industrial and municipal odor control, industrial and commercial air toxics controls, and "sick building syndrome." In our own company's work, we are finding new potential applications every month in such diverse areas as reducing pollution from closed solid waste landfills and reducing emissions of volatile organic compounds from lumber drying.

Our own company projects greater than $25 million in sales by the year 1999, with potentially 250 or more jobs created in Oregon. This estimate is based on our ability to raise capital in a timely fashion - our total needs by 1999 will exceed $5 million in equity investments in order to reach the projected sales goals and job targets.

The foreign market potential, particularly for odor control and industrial air pollution control in the Asian-Pacific markets, is equally large. We believe that the potential for all environmental biotechnologies, including those for cleaning up contaminated groundwater and industrial wastewater discharges, will be greater than $1 billion annually in the Asian-Pacific markets by the year 2000. As usual in the environmental technology industry, our most significant competitors will be Japanese and European companies. Without strong Federal assistance in promoting sales of our technologies in these markets, we will likely lose out in acquiring market share and industry dominance, with a consequent reduction in domestic job growth.

3. BARRIERS TO EFFECTIVE COMMERCIALIZATION

There are many barriers to effective commercialization of this exciting and valuable technology. Some are being discussed on other panels today, such as access to capital. Some are uniquely in the province of government, others exist in the market place. In the government arena, there are several important things that can be done to overcome barriers to commercialization. Each of these barriers is discussed briefly, and a proposal is made for dealing with it.

a. Overall Support: The Federal Government needs to make a firm commitment to supporting these technologies. Some agency efforts stand out, for example, EPA's "Bioremediation Field Initiative," in existence since 1989, and the Air Force Center for Environmental Excellence (AFCEE) with its commitment to bioventing and in-situ bioremediation for base cleanups. AFCEE is located at Brooks AFB in San Antonio, Texas.

PROPOSAL 1: Other agencies with strong research and remediation spending, such as the US Department of Energy, need to make similar commitments to bioremediation research and field trials. DOE's $5 billion remediation budget is nearly half of all Federal remediation money.

b. Research Support: Our company has received support this year from the US Air Force, under the SBIR program, with a Phase 1 project looking at the use of chemical catalysts in enhancing bioremediation of contaminated soils. We hope to continue this project into a Phase 2 portion, beginning next year. However, I must tell you that the Federal research support for the SBIR program, which funds promising research projects submitted by small businesses, is severely lacking in money. Agencies routinely receive $20 to $40 million in proposals for each $1 million they fund. EPA's SBIR program this year gave out only 20 awards nationally (and received nearly 400 proposals, many of them I am sure of high quality).

PROPOSAL 2: The Federal commitment to the important SBIR program, which supports basic research, particularly in the Phase 1 projects, should be increased ten-fold in the area of environmental biotechnology. The payoff will be increased development of new technologies that will reduce the costs of Federal remediation projects and increase American ability to sell environmental biotechnology to both domestic and international markets.

Our company has proposed a major three-year research program under the Department of Commerce/National Institute of Standards and Technology (NIST) "Advanced Technology Program, " totalling $1.6 million, with $1.1 million from the Federal Government. We are currently under consideration for such an award, having been recommended into the final competition as one of 83 from among 963 companies who made an abbreviated proposal. However, there is only $20 million budgeted for the first "General Competition," which has attracted nearly 400 finalists (not every was required to submit an abbreviated proposal.) To date, NIST has not targeted the environmental biotechnology industry for any of the "special competitions." This means that we have to compete with all non-targeted technologies and all sizes of companies for a relatively small $20 million pool (enough for 10 to 15 awards nationwide).

PROPOSAL 3: NIST should be directed to hold a Special Competition for Environmental Biotechnology during FY 1995, with at least $20 million in available funds, and to increase that amount to at least $40 million in FY 1996.

c. Field Demonstrations: Field demonstrations are an extremely cheap, quick and valuable way for the Federal Government to assist in the commercialization of new environmental biotechnology. In these programs, which could be easily held at a number of DOD, DOE and EPA contaminated sites, the pollution is already present. The Federal government should invite proposals in which new technology is brought to the site, set up at government expense and evaluated over a reasonable 6 to 12 month time period. The U.S. Navy has begun such a program through the Southwest Facilities Command at the North Island Naval Air Station in San Diego, California. Some 400 companies proposed in May of 1994, 38 were chosen for detailed evaluation and 8 contracts were eventually awarded. One successful company is paying $165,000 of its own money to participate in the evaluation process.

PROPOSAL 4: Each Federal agency with significant remediation spending projections should be required to set aside one or more significant demonstration sites, in each EPA region where it has remediation projects, for demonstrations of environmental biotechnology products and processes, with an evaluation process that guarantees that the evaluation of pilot and full-scale demonstrations will be widely publicized throughout the Federal Government's engineering community.

d. Technology Certifications: One of the barriers to adoption of new technology is simply market acceptance that it works. Many private and public agency clients are reluctant to spend extra funds on research and related evaluations, leaving little option for business to get independent verification of the feasibility, reliability, relative technical merit and cost-effectiveness of remediation technologies.

PROPOSAL 5: The Federal Government should designate EPA as a Lead Agency in developing technology certification programs for each federal agency with significant remediation spending, particularly focusing on remediation problems common to several federal agencies (such as underground storage tank fuel leaks and spills of chlorinated solvents). Such certification programs should focus on emerging technology areas such as environmental biotechnology and should involve federal funding for evaluations, with business responsible for furnishing the products or processes for evaluation.

We believe that the rapid commercialization of environmental biotechnology and the full realization of its export potential requires close monitoring and decisive action by the Federal Government. To date, the Federal research effort has documented promising applications of early stages of this technology, particularly for applications such as soil bioremediation. But more needs to be done, ranging from basic microbiological research to field demonstrations, product evaluations, technology certifications and export promotion. I would be pleased to answer your questions and to address further the issues raised in this testimony.

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